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42 CFR Parts 403, 405, 410, et al.
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, 411, 414, 418, 424, 484, and 486

[CMS–1429–FC]

RIN 0938–AM90

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule refines the resource-based practice expense relative value units (RVUs) and makes other changes to Medicare Part B payment policy. These policy changes concern: supplemental survey data for practice expense; updated geographic practice cost indices for physician work and practice expense; updated malpractice RVUs; revised requirements for supervision of therapy assistants; revised payment rules for low osmolar contrast media; changes to payment policies for physicians and practitioners managing dialysis patients; clarification of care plan oversight requirements; revised requirements for supervision of diagnostic psychological testing services; clarifications to the policies affecting therapy services; revised requirements for assignment of Medicare claims; addition to the list of telehealth services; and, several coding issues. We are making these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services.

This final rule also addresses the following provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–17) (MMA): coverage of an initial preventive physical examination; coverage of cardiovascular (CV) screening blood tests; coverage of diabetes screening tests; incentive payment improvements for physicians in shortage areas; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; coverage of routine costs associated with certain clinical trials of category A devices as defined by the Food and Drug Administration; hospice consultation service; indexing the Part B deductible to inflation; extension of coverage of intravenous immune globulin (IVIG) for the treatment in the home of primary immune deficiency diseases; revisions to reassignment provisions; and, payment for diagnostic mammograms, physicians' services associated with drug administration services and coverage of religious nonmedical health care institution items and services to the beneficiary's home.

In addition, this rule updates the codes subject to the physician self-referral prohibition, discusses payment for set-up of portable x-ray equipment, discusses the third five-year refinement of work RVUs, and solicits comments on potentially misvalued work RVUs.

We are also finalizing the calendar year (CY) 2004 interim RVUs and are issuing interim RVUs for new and revised procedure codes for CY 2005.

As required by the statute, we are announcing that the physician fee schedule update for CY 2005 is 1.5 percent, the initial estimate for the sustainable growth rate for CY 2005 is 4.3, and the conversion factor for CY 2005 is $37.8975.

DATES: *Effective Date:* These regulations are effective on January 1, 2005.

Applicability Date: Section 623 of the MMA, that is, the case-mix portion of the revised composite payment methodology and the budget neutrality adjustment required by the MMA, is applicable on April 1, 2005.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 3, 2005.

ADDRESSES: In commenting, please refer to file code CMS–1429–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1429–FC, P.O. Box 8012, Baltimore, MD 21244–8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number 800–743–3951 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Pam West (410) 786–2302 (for issues related to Practice Expense, Respiratory Therapy Coding, and Therapy Supervision).

Rick Ensor (410) 786–5617 (for issues related to Geographic Practice Cost Index (GPCI) and malpractice RVUs).

Craig Dobyski (410) 786–4584 (for issues related to list of telehealth services or payments for physicians and practitioners managing dialysis patients).

Bill Larson or Tiffany Sanders (410) 786–7176 (for issues related to coverage of an initial preventive physical examination).

Cathleen Scally (410) 786–5714 (for issues related to payment of an initial preventive physical examination).

Joyce Eng (410) 786–7176 (for issues related to coverage of cardiovascular screening tests).

Betty Shaw (410) 786–7176 (for issues related to coverage of diabetes screening tests).

Anita Greenberg (410) 786–0548 (for issues related to payment of cardiovascular and diabetes screening tests).

David Worgo (410) 786–5919, (for issues related to incentive payment

improvements for physicians practicing in shortage areas).

Angela Mason or Jennifer Fan (410) 786–0548 (for issues related to payment for covered outpatient drugs and biologicals).

David Walczak (410) 786–4475 (for issues related to reassignment provisions).

Henry Richter (410) 786–4562 (for issues related to payments for ESRD facilities).

Steve Berkowitz (410) 786–7176 (for issues related to coverage of routine costs associated with certain clinical trials of category A devices).

Terri Deutsch (410) 786–9462 (for issues related to hospice consultation services).

Karen Daily (410) 786–7176 (for issues related to clinical conditions for payment of covered items of durable medical equipment).

Dorothy Shannon (410) 786–3396 (for issues related to outpatient therapy services performed ''incident to'' physicians' services).

Roberta Epps (410) 786–5919 (for issues related to low osmolar contrast media or supervision of diagnostic psychological testing services).

Gail Addis (410) 786–4522 (for issues related to care plan oversight).

Jean-Marie Moore (410) 786–3508 (for issues related to religious nonmedical health care institution services).

Diane Milstead (410) 786–3355 or Gaysha Brooks (410) 786–9649 (for all other issues).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on the following issues: interim RVUs for selected procedure codes identified in Addendum C; zip code areas for Health Professional Shortage Areas (HPSAs); the coverage of religious nonmedical health care institution items and services to the beneficiary's home; the physician self referral designated health services listed in tables 20 and 21; the third five-year refinement of work RVUs for services furnished beginning January 1, 2007; and, potentially misvalued work RVUs for all services in the CY 2005 physician fee schedule. You can assist us by referencing the file code CMS–1429–FC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are processed, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 800–743–3951.

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This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The web site address is: *http://www.access.gpo.gov/nara/index.html.*

Information on the physician fee schedule can be found on the CMS homepage. You can access this data by using the following directions:

1. Go to the CMS homepage (*http://www.cms.hhs.gov*).

2. Place your cursor over the word ''Professionals'' in the blue area near the top of the page. Select ''physicians'' from the drop-down menu.

3. Under ''Policies/Regulations'' select ''Physician Fee Schedule.''

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents. Some of the issues discussed in this preamble affect the payment policies but do not require changes to the regulations in the Code of Federal Regulations. Information on the regulation's impact appears throughout the preamble and is not exclusively in section VII.

Table of Contents

In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AAA Abdominal aortic aneurysm
AAFP American Academy of Family Physicians
AAKP American Association of Kidney Patients
AANA American Association of Nurse Anesthetists
ABI Ankle brachial index
ABN Advanced beneficiary notice
ACC American College of Cardiology
ACLA American Clinical Laboratory Association
ACP American College of Physicians
ACPM American College of Preventative Medicine
ACR American College of Radiology
ADLs Activities of daily living
AFROC Association of Freestanding Radiation Oncology Centers
AGS American Geriatric Society
AHA American Heart Association
AMA American Medical Association
AOA American Osteopathic Association
APA Administrative Procedures Act
APTA American Physical Therapy Association
ASA American Society of Anesthesiologists
ASCP American Society for Clinical Pathology
ASN American Society of Nephrology
ASP Average sales price
ASTRO American Society for Therapeutic Radiation Oncology
ATA American Telemedicine Association
AWP Average wholesale price
BBA Balanced Budget Act of 1997
BBRA Balanced Budget Refinement Act of 1999
BIPA Benefits Improvement and Protection Act of 2000
BLS Bureau of Labor Statistics
BMI Body mass index
BSA Body surface area
CAH Critical access hospital
CAP College of American Pathologists
CAPD Continuous ambulatory peritoneal dialysis
CCPD Continuous cycling peritoneal dialysis
CDC Centers for Disease Control and Prevention
CF Conversion factor
CFR Code of Federal Regulations
CLIA Clinical Laboratory Improvement Amendment
CMA California Medical Association
CMS Centers for Medicare & Medicaid Services
CNMs Certified nurse midwives
CNS Clinical nurse specialist
COPD Chronic obstructive pulmonary disease
CORF Comprehensive outpatient rehabilitation facilities
CPEP Clinical Practice Expert Panel
CPI Consumer Price Index
CPO Care Plan Oversight
CPT [Physicians'] Current Procedural Terminology [4th Edition, 2002, copyrighted by the American Medical Association]
CRNAs Certified Registered Nurse Anesthetists
CT Computed tomography
CV Cardiovascular
CY Calendar year
DEXA Dual energy x-ray absorptiometry
DHS Designated health services
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DMERC Durable medical equipment regional carrier
DOI Departments of Insurance
DRE Digital rectal exam
DRG Diagnosis-related groups
DVT Deep venous thrombosis
EKG Electrocardiogram
E/M Evaluation and management
EPO Erythropoeitin
ESRD End-stage renal disease
FAX Facsimile
FMR Fair market rental
FQHC Federally qualified healthcare center
FR Federal Register
FY Fiscal year
GAF Geographic adjustment factor
GPCI Geographic practice cost index
GTT Glucose tolerance test
HBO Hyperbaric oxygen
HCPAC Health Care Professional Advisory Committee
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HHS [Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
HOCM High osmolar contrast media
HPSA Health professional shortage area
HRSA Health Resources and Services Administration
HsCRP high sensitivity C-reactive protein
HUD Housing and Urban Development
IDTFs Independent diagnostic testing facilities
IMRT Intensity modulated radiation therapy
IOM Internet Only Manual
IPD Intermittent peritoneal dialysis
IPPE Initial preventive physical examination
IPPS Inpatient prospective payment system
ISO Insurance Services Office
IVIG Intravenous immune globulin
JUAs Joint underwriting associations
KCP Kidney Care Partners
KECC Kidney Epidemiology and Cost Center
LCD Local coverage determination
LMRP Local medical review policies
LOCM Low osmolar contrast media
LUPA Low utilization payment adjustment
MCM Medicare Carrier Manual
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MGMA Medical Group Management Association
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MPFS Medicare physician fee schedule
MSA Metropolitan statistical area
NAMCS National Ambulatory Medical Care Survey
NCD National coverage determination
NCIPC National Center for Injury Prevention and Control
NDC National drug code
NIH National Institutes of Health
NP Nurse practitioner
NPP Nonphysician practitioners
OASIS Outcome and Assessment Information Set
OBRA Omnibus Budget Reconciliation Act
OIG Office of Inspector General
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OT Occupational therapy
OTA Occupational therapist assistant
OTPP Occupational therapists in private practice
PA Physician assistant
PAD Peripheral arterial disease
PC Professional component
PCF Patient compensation fund
PD Peritoneal dialysis
PEAC Practice Expense Advisory Committee
PET Positron emission tomography
PFS Physician Fee Schedule
PHSA Public Health Services Act
PIAA Physician Insurers Association of America
PIN Provider identification number
PLI Professional liability insurance
POS Prosthetics, orthotics and supplies
PPI Producer price index
PPS Prospective payment system
PRA Paperwork Reduction Act
PSA Physician scarcity area
PT Physical therapy
PTA Physical therapist assistant
PTPP Physical therapists in private practice
PVD Peripheral vascular disease
RFA Regulatory Flexibility Act

RHC Rural health clinic
RHHI Regional home health intermediary
RIA Regulatory impact analysis
RN Registered nurse
RNHCI Religious nonmedical health care institution
RPA Renal Physicians Association
RT Respiratory therapy
RTs Respiratory therapists
RUC [AMA's Specialty Society] Relative [Value] Update Committee
RUCA Rural-Urban commuting area
RVU Relative value unit
SAF Standard analytic file
SCHIP State Child Health Insurance Program
SGR Sustainable growth rate
SHIPs State Health Insurance Assistance Programs
SIR Society for Interventional Radiology
SLP Speech language pathology
SMR Standardized mortality ratio
SMS [AMA's] Socioeconomic Monitoring System
SNF Skilled nursing facility
TC Technical component
UAF Update adjustment factor
URR Urea reduction ratios
USPSTF U.S. Preventive Services Task Force

I. Background

A. Legislative History

Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services'' since January 1, 1992. The Act requires that payments under the fee schedule be based on national uniform relative value units (RVUs) reflecting the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense, and malpractice expense. Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs may not cause total physician fee schedule payments to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs cause expenditures to change by more than $20 million, we must make adjustments to ensure that they do not increase or decrease by more than $20 million.

B. Published Changes to the Fee Schedule

The July 2000 and August 2003 proposed rules ((65 FR 44177) and (68 FR 49030), respectively), include a summary of the final physician fee schedule rules published through February 2003.

In the November 7, 2003 final rule, we refined the resource-based practice expense RVUs and made other changes to Medicare Part B payment policy. The specific policy changes concerned: the Medicare Economic Index; practice expense for professional component services; definition of diabetes for diabetes self-management training; supplemental survey data for practice expense; geographic practice cost indices; and several coding issues. In addition, this rule updated the codes subject to the physician self-referral prohibition. We also made revisions to the sustainable growth rate and the anesthesia conversion factor. Additionally, we finalized the CY 2003 interim RVUs and issued interim RVUs for new and revised procedure codes for CY 2004.

As required by the statute, we announced that the physician fee schedule update for CY 2004 was −4.5 percent; that the initial estimate of the sustainable growth rate for CY 2004 was 7.4 percent; and that the conversion factor for CY 2004 was $35.1339.

Subsequent to the November 7, 2003 final rule, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–17) (MMA). On January 7, 2004, an interim final rule was published to implement provisions of the MMA applicable in 2004 to Medicare payment for covered drugs and physician fee schedule services. These provisions included—

- Revising the current payment methodology for Medicare Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis;
- Making changes to Medicare payment for furnishing or administering drugs and biologicals;
- Revising the geographic practice cost indices;
- Changing the physician fee schedule conversion factor. (Note: The 2004 physician fee schedule conversion factor is $37.3374); and
- Extending the ''opt-out'' provisions of section 1802(b)(5)(3) of the Act to dentists, podiatrists, and optometrists.

The information contained in the January 7, 2004 interim final rule concerning payment under the physician fee schedule superceded information contained in the November 7, 2003 final rule to the extent that the two are inconsistent.

C. Components of the Fee Schedule Payment Amounts

Under the formula set forth in section 1848(b)(1) of the Act, the payment amount for each service paid under the physician fee schedule is the product of three factors: (1) A nationally uniform relative value unit (RVU) for the service; (2) a geographic adjustment factor (GAF) for each physician fee schedule area; and (3) a nationally uniform conversion factor (CF) for the service. The CF converts the relative values into payment amounts.

For each physician fee schedule service, there are three relative values: (1) An RVU for physician work; (2) an RVU for practice expense; and (3) an RVU for malpractice expense. For each of these components of the fee schedule, there is a geographic practice cost index (GPCI) for each fee schedule area. The GPCIs reflect the relative costs of practice expenses, malpractice insurance, and physician work in an area compared to the national average for each component.

The general formula for calculating the Medicare fee schedule amount for a given service in a given fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU practice expense × GPCI practice expense) + (RVU malpractice x GPCI malpractice)] × CF

The CF for calendar year (CY) 2005 appears in section X. The RVUs for CY 2005 are in Addendum B. The GPCIs for CY 2005 can be found in Addendum D.

Section 1848(e) of the Act requires us to develop GAFs for all physician fee schedule areas. The total GAF for a fee schedule area is equal to a weighted average of the individual GPCIs for each of the three components of the service. In accordance with the statute, however, the GAF for the physician's work reflects one-quarter of the relative cost of physician's work compared to the national average.

D. Development of the Relative Value System

1. Work Relative Value Units

Approximately 7,500 codes represent services included in the physician fee schedule. The work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes in a cooperative agreement with us. In constructing the vignettes for the original RVUs, Harvard worked with expert panels of physicians and obtained input from physicians from numerous specialties.

The RVUs for radiology services were based on the American College of Radiology (ACR) relative value scale, which we integrated into the overall physician fee schedule. The RVUs for anesthesia services were based on RVUs from a uniform relative value guide. We established a separate CF for anesthesia services, and we continue to recognize

time as a factor in determining payment for these services. As a result, there is a separate payment system for anesthesia services.

2. Practice Expense and Malpractice Expense Relative Value Units

Section 1848(c)(2)(C) of the Act requires that the practice expense and malpractice expense RVUs equal the product of the base allowed charges and the practice expense and malpractice percentages for the service. Base allowed charges are defined as the national average allowed charges for the service furnished during 1991, as estimated using the most recent data available. For most services, we used 1989 charge data aged to reflect the 1991 payment rules, because those were the most recent data available for the 1992 fee schedule.

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, required us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician's service. As amended by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, section 1848(c) required the new payment methodology to be phased in over 4 years, effective for services furnished in 1999, with resource-based practice expense RVUs becoming fully effective in 2002. The BBA also required us to implement resource-based malpractice RVUs for services furnished beginning in 2000.

II. Provisions of the Proposed Rule Related to the Physician Fee Schedule

In response to the publication of the August 5, 2004 proposed rule (69 FR 47488), we received approximately 9,302 comments. We received comments from individual physicians, health care workers, professional associations and societies, and beneficiaries. The majority of the comments addressed the proposals related to ''incident to'' therapy services, GPCI, diagnostic psychological testing, and drug issues including average sales price (ASP).

The proposed rule discussed policies that affected the number of RVUs on which payment for certain services would be based. The proposed rule also discussed policies related to implementation of the MMA. RVU changes implemented through this final rule are subject to the $20 million limitation on annual adjustments contained in section 1848(c)(2)(B)(ii)(II) of the Act.

After reviewing the comments and determining the policies we would implement, we have estimated the costs and savings of these policies and discuss in detail the effects of these changes in the Regulatory Impact Analysis in section XIV.

For the convenience of the reader, the headings for the policy issues correspond to the headings used in the August 5, 2004 proposed rule. More detailed background information for each issue can be found in the August 5, 2004 proposed rule.

A. Resource-Based Practice Expense Relative Value Units

1. Resource-Based Practice Expense Legislation

Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Social Security Act (the Act) and required us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician's service beginning in 1998. Until that time, physicians' practice expenses were established based on historical allowed charges.

In developing the methodology, we were to consider the staff, equipment, and supplies used in providing medical and surgical services in various settings. The legislation specifically required that, in implementing the new system of practice expense RVUs, we apply the same budget-neutrality provisions that we apply to other adjustments under the physician fee schedule.

Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, amended section 1848(c)(2)(C)(ii) of the Act and delayed the effective date of the resource-based practice expense RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based practice expense RVUs to resource-based RVUs.

Further legislation affecting resource-based practice expense RVUs was included in the Medicare, Medicaid and State Child Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) enacted on November 29, 1999. Section 212 of the BBRA amended section 1848(c)(2)(C)(ii) of the Act by directing us to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations. These data would supplement the data we normally collect in determining the practice expense component of the physician fee schedule for payments in CY 2001 and CY 2002. (The 1999 and 2003 final rules (64 FR 59380 and 68 FR 63196, respectively, extended the period during which we would accept supplemental data.)

2. Current Methodology for Computing the Practice Expense Relative Value Unit System

In the November 2, 1998 final rule (63 FR 58910), effective with services furnished on or after January 1, 1999, we established at 42 CFR 414.22(b)(5) a new methodology for computing resource-based practice expense RVUs that used the two significant sources of actual practice expense data we have available—the Clinical Practice Expert Panel (CPEP) data and the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) data. The CPEP data were collected from panels of physicians, practice administrators, and nonphysicians (for example registered nurses) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physicians service in both the office setting and out-of-office setting. The AMA's SMS data provided aggregate specialty-specific information on hours worked and practice expenses. The methodology was based on an assumption that current aggregate specialty practice costs are a reasonable way to establish initial estimates of relative resource costs for physicians' services across specialties. The methodology allocated these aggregate specialty practice costs to specific procedures and, thus, can be seen as a ''top-down'' approach.

Also in the November 2, 1998 final rule, in response to comments, we discussed the establishment of the Practice Expense Advisory Committee (PEAC) of the AMA's Specialty Society Relative Value Update Committee (RUC), which would review code'specific CPEP data during the refinement period. This committee would include representatives from all major specialty societies and would make recommendations to us on suggested changes to the CPEP data.

As directed by the BBRA, we also established a process (*see* 65 FR 65380) under which we would accept and use, to the maximum extent practicable and consistent with sound data practices, data collected by entities and organizations to supplement the data we normally collect in determining the practice expense component of the physician fee schedule.

a. Major Steps

A brief discussion of the major steps involved in the determination of the practice expense RVUs follows. (Please see the November 1, 2001 final rule (66 FR 55249) for a more detailed explanation of the top-down methodology.)

- *Step 1*—Determine the specialty specific practice expense per hour of physician direct patient care. We used the AMA's SMS survey of actual aggregate cost data by specialty to determine the practice expenses per hour for each specialty. We calculated the practice expenses per hour for the specialty by dividing the aggregate practice expenses for the specialty by the total number of hours spent in patient care activities.
- *Step 2*—Create a specialty-specific practice expense pool of practice expense costs for treating Medicare patients. To calculate the total number of hours spent treating Medicare patients for each specialty, we used the physician time assigned to each procedure code and the Medicare utilization data. The primary sources for the physician time data were surveys submitted to the AMA's RUC and surveys done by Harvard for the establishment of the work RVUs. We then multiplied the physician time assigned per procedure code by the number of times that code was billed by each specialty, and summed the products for each code, by specialty, to get the total physician hours spent treating Medicare patients for that specialty. We then calculated the specialty-specific practice expense pools by multiplying the specialty practice expenses per hour (from step 1) by the total Medicare physician hours for the specialty.
- *Step 3*—Allocate the specialty-specific practice expense pool to the specific services (procedure codes) performed by each specialty. For each specialty, we divided the practice expense pool into two groups based on whether direct or indirect costs were involved and used a different allocation basis for each group.

(i) Direct costs—For direct costs (which include clinical labor, medical supplies, and medical equipment), we used the procedure-specific CPEP data on the staff time, supplies, and equipment as the allocation basis. For the separate practice expense pool for services without physician work RVUs, we have used, on an interim basis, 1998 practice expense RVUs to allocate the direct cost pools.

(ii) Indirect costs—To allocate the cost pools for indirect costs, including administrative labor, office expenses, and all other expenses, we used the total direct costs, or the 1998 practice expense RVUs, in combination with the physician fee schedule work RVUs. We converted the work RVUs to dollars using the Medicare CF (expressed in 1995 dollars for consistency with the SMS survey years).

- *Step 4*—The direct and indirect costs are then added together to attain the practice expense for each procedure, by specialty. For procedures performed by more than one specialty, the final practice expense allocation was a weighted average of practice expense allocations for the specialties that perform the procedure, based on the frequency with which each specialty performs the procedure on Medicare patients.

b. Other Methodological Issues

i. Nonphysician Work Pool

As an interim measure, until we could further analyze the effect of the top-down methodology on the Medicare payment for services with physician work RVUs equal to zero (including the technical components of radiology services and other diagnostic tests), we created a separate practice expense pool. We first used the average clinical staff time from the CPEP data and the ''all physicians'' practice expense per hour to create the pool. In the December 2002 final rule, we changed this policy and now use the total clinical staff time and the weighted average specialty-specific practice expense per hour for specialties with services in this pool. In the next step, we used the adjusted 1998 practice expense RVUs to allocate this pool to each service. Also, for all radiology services that are assigned physician work RVUs, we used the adjusted 1998 practice expense RVUs for radiology services as an interim measure to allocate the direct practice expense cost pool for radiology.

A specialty society may request that its services be removed from the nonphysician work pool. We have removed services from the nonphysician work pool if the requesting specialty predominates utilization of the service.

ii. Crosswalks for Specialties Without Practice Expense Survey Data

Since many specialties identified in our claims data did not correspond exactly to the specialties included in the SMS survey data, it was necessary to crosswalk these specialties to the most appropriate SMS specialty.

iii. Physical Therapy Services

Because we believe that most physical therapy services furnished in physicians' offices are performed by physical therapists, we crosswalked all utilization for therapy services in the CPT 97000 series to the physical and occupational therapy practice expense pool.

3. Practice Expense Proposals for Calendar Year 2005

a. Supplemental Practice Expense Surveys

i. Survey Criteria and Submission Dates

As required by the BBRA, we established criteria to evaluate survey data collected by organizations to supplement the SMS survey data used in the calculation of the practice expense component of the physician fee schedule. The deadline for submission of supplemental data to be considered in CY 2006 is March 1, 2005.

ii. Survey by the College of American Pathologists (CAP)

In the August 5, 2004 rule, we proposed to incorporate the CAP survey data into the practice expense methodology and to implement a change to the practice expense methodology to calculate the technical component RVUs for pathology services as the difference between the global and professional component RVUs. (This technical change was proposed in the June 28, 2002 **Federal Register** (67 FR 43849), but, at the specialty's request, we delayed implementation of this change for pathology services to permit evaluation of the combined effects of the use of the new survey data along with this technical change to the methodology.) We proposed to use the following practice expense per hour figures for specialty 69—Independent Laboratory.

TABLE 1: Practice Expense Per Hour Figures for Specialty 69--Independent Laboratory

Specialty	Clinical Staff	Admin. Staff	Office Expense	Medical Supplies	Medical Equipment	Other	Total
Independent Laboratory	$66.5	$20.2	$15.0	$15.8	$6.9	$16.9	$141.1

Comment: Specialty organizations representing clinical laboratories and pathologists expressed support for the use of the CAP supplemental survey data and urged us to finalize this proposal.

Response: We will incorporate the CAP survey data into the practice expense methodology and implement the proposed change to the practice expense methodology to calculate the technical component RVUs for pathology services as the difference between the global and professional component RVUs.

iii. Submission of Supplemental Surveys

We received surveys from the American College of Cardiology (ACC), the American College of Radiology (ACR), and the American Society for Therapeutic Radiation Oncology (ASTRO). Our contractor, The Lewin Group, evaluated the data and recommended that we accept the data from the ACC and the ACR, but indicated that the survey from ASTRO did not meet the precision criteria established for supplemental surveys and, thus, did not recommend using the ASTRO survey results at this time. We agreed with these recommendations. However, as explained in the August 5, 2004 proposed rule, the ACR and the ACC requested that we not use the data until we have a stable and global solution that is workable for all specialties that are currently paid using the nonphysician work pool. We agreed with these requests and proposed delaying use of these supplemental surveys until issues related to the nonphysician work pool can be addressed.

Comment: The ACR expressed appreciation for our acceptance of the supplemental data and for our proposal to delay implementation until next year, as they had requested, to allow further time to examine the issue of the nonphysician work pool. The Society for Interventional Radiology (SIR) also expressed support for the use of the ACR data and the delay in implementation.

Response: We look forward to working with these and other specialties as we seek a permanent solution to practice expense issues associated with the nonphysician work pool.

Comment: ASTRO stated that they appreciate the opportunity to submit data and, that they understand we will not be using the data in 2005. ASTRO further commented that, due to the specific practice patterns and practice environment of radiation oncology, new data, regardless of the response rate, may not meet the criteria. ASTRO further stated that they will continue to work with CMS and with the Lewin Group as this issue is analyzed. The Association of Freestanding Radiation Oncology Centers (AFROC) expressed concern that freestanding centers that have higher costs than hospital-based centers were underrepresented by the ASTRO survey. They also expressed concern about the reference in the Lewin Group report to crosswalking radiation oncology costs from another specialty. In addition, AFROC argued that we should not average costs associated with freestanding centers with those that are hospital-based, because the costs would be understated. They urged us to ensure that any assumption regarding representativeness of any survey data is justified.

Response: We will take these comments into consideration as we continue to work with these groups concerning the supplemental survey data. We currently have no plans to propose a practice expense crosswalk for radiation oncology.

Comment: The ACC expressed appreciation that we are not eliminating the nonphysician workpool until methodologic issues are addressed. While they support the delay in implementing their supplemental survey data, they believe that the contractor's suggestion that the ACC survey data could be blended with the existing SMS survey data is invalid for two reasons: (1) The suggestion that similar changes to physician practice (for example, increased use of technology) may have occurred throughout all physician services is an unfounded speculation because few other specialties are as technologically driven as cardiology; and (2) other supplemental data has not been blended and all specialties must be treated consistently.

Response: We will take these comments into consideration as part of the evaluation and discussion of the cardiology survey data in next year's proposed rule.

Comment: The American Urological Association requested that, as we explore alternate sources of data and consider how to incorporate new practice expense data into the methodology, we find a way to incorporate recently collected specialty supplemental data into the new efforts. They also requested that we clarify whether we would apply the budget neutrality exemption to any increases in drug administration PE RVUs that result from the use of urology survey data that will be submitted under the supplemental survey process.

Response: We anticipate that we would incorporate all accepted supplemental survey data into any comprehensive changes to the nonphysician work pool.

As we explained in the January 7, 2004 **Federal Register** (69 FR 1093 through 1094), section 303(a)(1) of the MMA modifies section 1848(c)(2)(B) of the Act to provide an exemption from the budget neutrality requirements in 2006 for further increases in the practice expense RVUs for drug administration that may result from using survey data from specialties meeting certain criteria. The survey must include expenses for the administration of drugs and biologicals and be submitted by a specialty that receives more than 40 percent of its 2002 Medicare revenues from drugs. Urology received more than 40 percent of its 2002 Medicare revenues from drugs. Therefore, if we were to receive a practice expense survey of urologists by March 1, 2005

that included expenses for the administration of drugs and biologicals and the survey met the criteria we have established (and those of section 1848(c)(2)(I)(ii) of the Act), we would exempt the change in the practice expense RVUs for drug administration services from the budget neutrality requirements of section 1848(c)(2)(B) of the Act.

b. Practice Expense Advisory Committee (PEAC)

Recommendations on CPEP Inputs for 2005

- CPEP Refinement Process.

In the August 5, 2004 proposed rule, we included the PEAC recommendations from meetings held in March and August 2003 and January and March 2004, which accounted for over 2,200 codes from many specialties. We also stated that future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC.

Comment: We received comments from the AMA that future practice expense issues, including the refinement of the remaining codes not addressed by the PEAC, would be handled by the RUC with the help of a new ad hoc committee, now termed the Practice Expense Review Committee (PERC), comprised of former PEAC members. The RUC also noted that their Practice Expense Subcommittee remains committed to reviewing improvements to the practice expense methodology.

The AMA and the RUC, as well as the specialty society representing neurological surgeons, noted their appreciation of our continued efforts to improve the direct practice expense data and to establish a reasonable methodology for determining practice expense relative values.

Response: We look forward to our continuing work with the AMA, the RUC and all the specialty societies on the refinement of the remaining codes and with ongoing practice expense issues.

Comment: The National Association for the Support of Long Term Care expressed concern about the dissolution of the PEAC and requested that we require the RUC to expand its membership to include a broad array of providers who are reimbursed under the physician fee schedule.

Response: Because the RUC is an independent committee, we are not in a position to set the requirements for RUC membership. However, we are confident that the RUC and the Health Care Professional Advisory Committee, which also sends practice expense recommendations directly to us, together represent two broad ranges of practitioners, both physician and nonphysician.

Comment: A specialty society suggested that there should be a process for fixing minor errors that are identified outside of the refinement process. The commenter also suggested that there should be a system to address individual exceptions to PEAC standard packages.

Response: If we have made errors, major or minor, in any part of our calculation of practice expense RVUs in this final rule, inform us as soon as possible so that we are able to correct them in the physician fee schedule correction notice. Any other revisions would have to be made in the next physician fee schedule rule. If a specialty society believes that a RUC decision is not appropriate, the society can always request that the decision be revisited or can discuss the issue with us at any time. For the concern with the standard packages adopted by the PEAC, it is our understanding that all presenters at the RUC have the opportunity to demonstrate that something other than the standard would be more appropriate.

- PEAC Recommendations.

We proposed to adopt nearly all of the PEAC recommendations. However, we disagreed with the PEAC recommendation for clinical labor time for CPT code 99183, Physician attendance and supervision of hyperbaric oxygen therapy, per session, and proposed a total clinical labor time of 112 minutes for this service.

Comment: Specialty societies representing interventional radiology and neurological surgeons, as well as the AMA, expressed appreciation for our acceptance of well over 2,000 PEAC refinements in this rule. However, the specialty society representing orthopaedic surgeons commented that some of our proposals appeared to be circumventing the PEAC process, in that we changed the PEAC recommendation for hyperbaric oxygen (HBO) therapy and proposed in-office inputs for two services rather than referring these to the RUC.

Response: We appreciate the hard work and perseverance on the part of the PEAC and the specialty societies that produced the recommended refinements for so many services. In addition, we do not believe that we circumvented the PEAC process in any way. We have the greatest respect for the PEAC and RUC recommendations that we received. However, we do have the final responsibility for all payments made under the physician fee schedule, and this can lead to disagreement with a specific recommendation. The RUC itself has always demonstrated its understanding and respect for our responsibility in this regard. With regard to the two services that we priced in the office, we stated explicitly in the proposed rule that we were requesting that the RUC review the practice expense inputs.

Comment: The specialty society representing family physicians disagreed with our proposed changes to the PEAC recommendations for the clinical labor time for CPT code 99183, *Physician attendance and supervision of hyperbaric oxygen therapy, per session.* The commenter contended that a physician providing this service would probably have multiple hyperbaric oxygen chambers; therefore, staff would not be in constant attendance. However, the specialty society representing podiatrists supported this change in clinical staff time.

Response: Based on our concern that the PEAC recommendation of 20 minutes of clinical staff time during the intra-service period undervalued the clinical staff time, we proposed increasing this time to 90 minutes in the proposed rule. This was, of course, subject to comment. We believe there is some merit to the claim that the clinical staff may be monitoring more than one chamber at a time. Therefore, we are adjusting the time for the intra-service period from the proposed 90 minutes to 60 minutes in recognition of this point. We will continue our examination of this issue and entertain ongoing dialog with all interested organizations and individuals familiar with this service to assure the accuracy of the intra-service time.

Comment: The Cardiac Event Monitoring Provider Group Coalition expressed concern about the PEAC recommendations that would substantially reduce the clinical staff time associated with cardiac monitoring services. Of particular concern to the Coalition was the 70 percent reduction in time for CPT code 93271, the code for cardiac event monitoring, receipt of transmissions, and analysis. Although all these services are currently priced in the nonphysician work pool and this decrease in the staff times has no immediate impact, the commenter was concerned that, when the nonphysician work pool is eliminated, these services will be undervalued. The commenter also believed that the PEAC recommendations may not have reflected all the supplies and equipment utilized in these services and included a complete list of necessary supplies

and equipment. The American College of Cardiology (ACC) presented these services at the PEAC meeting and commented they had been unable to collect sufficient data so that the PEAC could make an appropriate recommendation.

Response: It is clear from the Coalition and ACC comments that more information is needed in order to ensure that the appropriate practice expense inputs are assigned to these services in the event that they are removed from the nonphysician work pool. We would be glad to work with the Coalition and the specialty society so that they can make a new presentation to the RUC this coming year.

• Adjustments To Conform With PEAC Standards

We also reviewed those codes that are currently unrefined or that were refined early in the PEAC process to apply some of the major PEAC-agreed standards. For the unrefined 10-day global services, we proposed to substitute for the original CPEP times the PEAC-agreed standard post-service office visit clinical staff times used for all 90-day and refined 10-day global services. We also proposed to eliminate the discharge day management clinical staff time from all but the 10 and 90-day global codes, substituting one post-service phone call if not already in the earlier data. Lastly, we proposed to delete any extra clinical staff time for post-visit phone calls for 10 and 90-day global service because that time is already included in the time allotted for the visits.

Comment: A specialty society representing family physicians supported the elimination of the discharge day management time assigned in the facility setting for all 0-day global services, as well as all the other adjustments we made to apply PEAC standards. However, several specialty societies representing gastroenterology and orthopaedics, as well as the American College of Physicians, did not agree with the deletion of the discharge day management time. These groups requested restoration of the six minutes allocated to the discharge day management for 0-day global services and argued that most 0-day services require as much staff time as do many 10-day global services performed in the outpatient setting. One of these commenters did not believe a rationale was provided for this change. Another commenter, although recommending that any future refinements take into account all of the PEAC standards, expressed concern regarding all of the above changes, suggesting that this could lead to additional anomalies and recommending that the revisions should be reviewed by the RUC.

Response: The PEAC recommended that the discharge day management time apply only to 10-day and 90-day global services and we were complying with this recommendation. We also believe that this PEAC recommendation is reasonable; it is hard to imagine what tasks a physician's clinical staff back in the office is performing for a patient during the period that the patient is undergoing a same-day procedure in the hospital outpatient department. However, the point made about 10-day global procedures is pertinent. We would suggest that the RUC reconsider whether the discharge day management clinical staff time should apply only to services that are typically performed in the inpatient setting. We also believe that it was appropriate to apply the PEAC standards to codes that were not refined or that were refined before the standards were developed. The application of these standards is not only fair, but can also help to avoid the possible rank order anomalies cited by the commenter.

Methacholine Chloride

The PEAC recommendations for CPT codes 91011 and 91052 included a supply input for methacholine chloride as the injected stimulant for these two services. In discussions with representatives from the gastroenterology specialty society subsequent to receipt of the PEAC recommendations, we learned this is incorrect. For the esophageal motility study, CPT code 91011, we proposed to include edrophonium as the drug typically used in this procedure. For the gastric analysis study, CPT code 91052, we were unable to identify the single drug that is most typically used with this procedure. We requested that commenters provide us with information on the drug that is most typically used for CPT code 91052, including drug dosage and price, so that it could be included in the practice expense database.

Comment: Several specialty societies representing allergists, pulmonologists and chest physicians, as well as the AMA, requested that the additional cost of methacholine be reflected in the RVUS for the bronchial challenge test, CPT code 95070. As an alternative, the specialty society representing allergists suggested that a HCPCS code could be created so that methacholine could be billed separately.

In response to our request for information about the supply inputs for CPT codes 91011 and 91052, the American Gastroenterological Association (AGA) indicated that edrophonium may be an appropriate supply proxy for CPT code 91011, but, in practice, other agents are more commonly used. However, they provided no additional information regarding these other agents. AGA also stated that the most commonly used drug for CPT code 91052 is pentagastrin, but betazole or histamine may also be used. Again, they did not provide further specific information.

Response: Because CPT code 95070 is valued in the nonphysician work pool, the PEAC's addition of methacholine to this procedure could not be captured by the practice expense RVUs. However, a J-code was established, J7674, *Methacholine chloride administered as inhalation solution through nebulizer, per 1mg,* so that this drug can be billed separately. Accordingly, we have deleted methacholine from the practice expense database.

For CPT code 91011, we have retained the drug edrophonium, and our proposed price of $4.67 per ml, as a supply in the practice expense database. However, we were not able to include a price for pentagastrin in the supply practice expense database for CPT code 91052. We will be happy to work with the specialty societies involved with both of these procedures to obtain accurate drug pricing for the 2006 fee schedule.

• Nursing Facility and Home Visits.

We proposed to adopt the direct practice expense input recommendations from the March 2003 PEAC meeting for CPT codes 99348 and 99350, two E/M codes for home visits, as well as the March 2004 PEAC recommendations for E/M codes for nursing home services (CPT codes 99301 through 99316).

Comment: A specialty group representing family physicians supported the acceptance of the PEAC recommendations for nursing facility visits, even though this resulted in a decrease for these services. The commenter stated that the decrease occurred because the original CPEP data was flawed and the clinical staff times were too high. The commenter also stated that the payments in the facility setting will increase for these services and that setting has the higher volume of visits. Other commenters representing long term care physicians, geriatricians and podiatrists expressed disappointment in these PEAC recommendations and stated that, while the PEAC did consider the views of long term care physicians, the PEAC failed to accept these views even though they were supported by data. These commenters believe the PEAC did not

recommend an appropriate increase based on a false assumption that the nursing home provides the staff. Another commenter contended that the new values do not adequately account for work performed by the physician's clinical staff. The commenter stated that the pre- and post-times for these codes are less than for the comparable office visit codes, even though it is clear that more clinical staff time is required for the nursing facility resident. One commenter suggested that these concerns would need to be addressed within the framework of the 5-year review. The specialty society representing homecare physicians also commented that, rather than challenging a flawed system, they will use the 5-year review process to have work and practice expense re-valuated for the home visit codes.

Response: While sympathetic to the concerns expressed by the long-term care physicians regarding the overall decrease in clinical staff time in the nursing facility E/M procedures, we believe the PEAC recommendations for these services to be reasonable. We also agree with commenters regarding the upcoming 5-year review process as a means to address the physician work component of these codes. To the extent that there is overlap between the physician time and the clinical labor practice expenses involved in a particular procedure, the 5-year review process can be utilized to address these issues. We encourage the home care physicians and the long-term care physicians to consider using the 5-year review process for these codes.

• Suggested Corrections to the CPEP Data.

Comment: The RUC and American Podiatric Medical Association identified a number of PEAC refinements from the August 2003 meeting that were not reflected in the practice expense database and asked that these be implemented. The RUC also asked us to correct the equipment times for all of the 90-day global services to correspond with the PEAC-refined clinical staff times for these codes.

Response: We have made the recommended corrections to our practice expense database.

Comment: The specialty society representing hematology noted the supply items missing from the practice expense database for CPT codes 36514 through 36516 that had been included in the CMS-accepted PEAC refinements.

Response: We regret the error. These items are incorporated into the practice expense database.

Comment: The specialty society representing pediatrics as well as the RUC commented that the PEAC recommendations also included a recommendation for a change in the global period for CPT code 54150, *Circumcision, using clamp or other device; newborn,* from a 10-day global to an ''xxx'' designation, which would mean the global period does not apply. This issue was not discussed in the proposed rule and the commenters requested that this change be reflected in the final rule.

Response: As stated by the commenters, this request was included in the PEAC recommendations but was inadvertently omitted from the proposed rule. We agree that the 10-day global period currently assigned to this procedure may not be appropriate because the physician performing the procedure most likely does not see the infant for a post-procedure visit. However, we believe that a 0-day global period rather than ''xxx'' should be assigned to this procedure. We generally use the ''xxx'' designation for diagnostic tests and no surgical procedure currently is designated as an ''xxx'' global service. We believe this will accomplish the same end because most any other service performed at the same time as the circumcision could be billed with the appropriate modifier. We are adjusting the practice expense database to delete any staff time, supplies and equipment associated with the post-procedure office visit.

Comment: Specialty societies representing dermatology stated that there was an error in the nonfacility practice expense RVUS for the Mohs micrographic surgery service, CPT code 17307, due to the omission of clinical staff time from the practice expense database.

Response: We have corrected the practice expense database to reflect the appropriate clinical staff time.

Comment: We received comments from the American College of Radiology (ACR) and Society of Nuclear Medicine noting that some of the codes used by their specialty were omitted from the listing of PEAC-refined codes that appeared in Addendum C in our proposed rule. They submitted a complete list of the codes that had gone through PEAC refinement, beginning at the first PEAC meeting in April 1999, and asked that we include these codes on the Addendum.

Response: We appreciate the specialty societies bringing to our attention that some of their codes were omitted from Addendum C and we have reviewed the codes on their submitted list. Addendum C was meant to list only those codes that were refined in this year's rule, and thus, only listed those refined by the PEAC from March and August 2003 and January and March 2004. However, it does appear that there is some confusion regarding what codes were refined during this period, particularly from the March 2004 meeting. We will work with all medical societies and the RUC to clarify the status of all the codes in question.

• Other Issues.

Comment: The RUC requested that we publish practice expense RVUs for all Medicare noncovered services for which the RUC has recommended direct inputs. We also received a request from the American Academy of Pediatrics to publish work and practice expense RVUs for the noncovered nasal or oral immunization services (CPT codes 90473 and 90474) and the visual acuity test (CPT code 99173).

Response: In the past, we have published the practice expense RVUs for only a small number of noncovered codes which are listed in our national payment files that can be accessed via our physician web page under ''Medicare Payment Systems'' as part of the public use files at *www.cms.hhs.gov/physicians/.* Because we have not yet established a consistent policy regarding the publication of RVUs for noncovered services, we will need to examine this issue further to carefully weigh the pros and cons of publishing these RVUs for noncovered services.

Comment: The American Speech-Language Hearing Association (ASHA) and the American Academy of Audiology (AAA), expressed concern about the reduction of practice expense RVUs for CPT code 92547, *Use of vertical electrodes (List separately in addition to code for primary procedure),* which resulted after the PEAC refinement. The commenters asked for our assistance to clarify a CPT instruction regarding this procedure because they believe it prevents the multiple billings of CPT 92547 in a given patient encounter.

Response: While we are sympathetic to the concerns expressed by ASHA and AAA, we also want to note that CPT code descriptors and accompanying coding instructions are proprietary to CPT. We would encourage these organizations to discuss this issue directly with the CPT editorial committee.

Comment: A specialty society representing vascular surgery expressed concern about the wide variations in practice expense RVUs that are sometimes derived under the current methodology. The commenter suggested that some outliers require additional focus to determine whether these are errors in the direct inputs or if they

reflect problems inherent in the methodology. According to the commenter, it would appear that some of the extreme variation is due to the high costs of certain disposable supplies in the office setting as well as high scaling factors. A few examples of outlier codes were provided. The commenter suggested that we consider an alternative methodology for payment of high-priced single-use items in the nonfacility setting.

Response: We agree with the commenter that the issue raised is one worth study and analysis. Unfortunately, this is not a task that can be accomplished in time for discussion in this final rule. We will be very willing to work with the specialty society and with the Practice Expense Subcommittee of the RUC, as well as any other interested parties, to work further on this issue that will only be magnified as more complex procedures are moved into the office setting.

Comment: A provider of radiology services questioned the reductions in practice expense for CPT code 77370, *Special medical radiation physics consultation.*

Response: The practice expense RVUs for CPT code 77370 decreased by 0.02 RVUs between last year's final rule and this year's proposed rule. This small decrease is due to the normal fluctuations resulting from updating our practice expense data.

c. Repricing of Clinical Practice Expense Inputs—Equipment

We use the practice expense inputs (the clinical staff, supplies, and equipment assigned to each procedure) to allocate the specialty-specific practice expense cost pools to the procedures performed by each specialty. The costs of the original equipment inputs assigned by the CPEP panels were determined in 1997 by our contractor, Abt Associates, based primarily on list prices from equipment suppliers. Subsequent to the CPEP panels, equipment has also been added to the CPEP data, with the costs of the inputs provided by the relevant specialty society. We only include equipment with costs equal to or exceeding $500 in our practice expense database because the cost per use for equipment costing less than $500 would be negligible. We also consider the useful life of the equipment in establishing an equipment cost per minute of use.

We contracted with a consultant to assist in obtaining the current price for each equipment item in our CPEP database. The consultant was able to determine the current prices for most of the equipment inputs and clarified the specific composition of each of the various packaged and standardized rooms or ophthalmology ''lanes'' currently identified in the equipment practice expense database (for example, mammography room or exam lane). We proposed to delete the current ''room'' designation for the radiopharmaceutical receiving area and, in its place, list separately the equipment necessary for each procedure as individual line items.

Also, we proposed to replace all surgical packs and trays in the practice expense database with the appropriate standardized packs that were recommended by the PEAC, either the basic instrument pack or the medium pack.

The useful life for each equipment item was also updated as necessary, primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' (1998 edition). We noted in the August 5, 2004 proposed rule that AHA would be publishing updated guidelines this summer and that we would reflect any updates in our final rule.

In addition, we proposed the following database revisions:

Assignment of Equipment Categories

We proposed that equipment be assigned to one of the following six categories: documentation, laboratory, scopes, radiology, furniture, rooms-lanes, and other equipment. These categories would also be used to establish a new numbering system for equipment that would more clearly identify them for practice expense purposes.

Consolidation and Standardization of Item Descriptions

We proposed combining items that appeared to be duplicative. For example, for two cervical endoscopy procedures, our contractor identified that the price of the LEEP system includes a smoke evacuation system but that system is also listed separately. We proposed to merge these two line items and reflect both prices in the price of the LEEP system.

These changes were reflected in Addendum D of the proposed rule.

Additionally, there were specific equipment items for which a source was not identified or for which pricing information was not found that were included in Table 2 of the August 5 proposed rule. Items that we proposed to delete from the database were also identified in this table. We requested that commenters, particularly the relevant specialty groups, provide us with the needed pricing information, including appropriate documentation. Also, we stated that if we were not able to obtain any verified pricing information for an item, we might eliminate it from the database.

Comment: The Society of Nuclear Medicine agreed with the deletion of the current room designation for radiopharmaceutical area and designation of categories for equipment. However, the society recommended that the category designation of ''radiology'' be changed to ''imaging equipment'' and ''other equipment'' be changed to ''non-imaging equipment'' to be inclusive of these modalities. The American College of Radiology also concurred with the elimination of the current room designation for radiopharmaceutical area.

Response: We agree that the term ''imaging equipment'' rather than the term ''radiology'' more accurately reflects current practice and have changed the practice expense database accordingly. However, it would be inappropriate to change the ''other equipment'' category to ''non-imaging equipment'' because there are items in other categories that would not be encompassed in the proposed title change.

Comment: The Society of Nuclear Medicine supplied information on the equipment item E51076 with the requested documentation.

Response: We have revised the practice expense database to reflect the information provided.

Comment: The American Society for Therapeutic Radiology and Oncology (ASTRO) submitted information and the requested documentation for fifteen items, often supplying two or more pricing sources.

Response: We greatly appreciate the information and have revised the practice expense database to reflect the information provided.

Comment: Commenters representing manufacturers and providers expressed concern about the reduction in payment (9 percent) for external counterpulsation (ECP), G0166. The commenters questioned the proposed change made to the life of the ECP equipment, from seven to five years, used for this service. Commenters did not believe this was supported by the AHA information (which indicated that similar diagnostic cardiovascular equipment has an equipment life of five years) and requested that this timeframe be applied to the ECP equipment for this service. The American College of Cardiology also questioned the change to the ECP equipment life. The commenters also questioned the allocation for maintenance and indirect costs applied under the practice expense methodology

as well as the time allocated for this service. As a final point, some of the commenters requested that we adjust the work RVUs assigned to this G-code to that of an echocardiogram (CPT code 93307) and include it in the nonphysician work pool.

Response: Based upon review of the information provided we have revised the equipment life to five years. The methodology used for the allocation for maintenance and indirect costs is consistent with our methodology. For the request to adjust the work RVUs for this service, we refer the commenters to section VI of this final rule where we are soliciting comments on services where the physician work may be misvalued.

Comment: The College of American Pathologists provided information on items listed in table 2: the DNA image analyzer (ACIS), and image analyzer (CAS system) code E13652. They noted that the CAS system is no longer marketed and that the ACIS system would be used in its place. Thus, they provided documentation on the price for the ACIS system.

Response: We appreciate the information and have made the necessary changes to the database.

Comment: The American College of Cardiology (ACC) agreed with the pricing for the ambulatory blood pressure monitor, provided prices for the ECG signal averaging system (E55035), but provided no documentation for these prices. They stated that the echocardiography digital acquisition ultrasound referenced in table 2 was no longer in the marketplace and that a digital workstation was now typically used. They requested that an appropriate equipment code be available for this item and provided a price range for this item (although without the supporting documentation). ACC also recommended that the pacemaker programmer (E55013) be removed from the equipment list because it is provided at no cost to the physician. Removal of this item from the PE database was also supported by a manufacturer that commented on the rule.

Response: We have removed the pacemaker programmer from the practice expense database. We will temporarily retain other items and prices for the 2005 physician fee schedule and request that ACC forward the documentation as soon as possible.

Comment: The American College of Radiology (ACR) provided partial information for the CAD processor unit and software. ACR also submitted information regarding the computer workstation for MRA and the mammography reporting software, but with insufficient documentation. For the various equipment items ACR listed for the mammography room, updated information was provided for a few of the items. ACR noted that they would submit documentation for all outstanding pieces of equipment when it is available. ACR did not agree with the room price for MRI and CT that was referenced in Addendum D and requested an extension so that they can work with us to accurately price these items.

Response: We will maintain current pricing for all equipment items and the mammography room on an interim basis, until sufficient documentation is provided.

Comment: The American Ophthalmology Association (AOA) and American Optometric Association both supplied pricing information along with the requested documentation for the computer, VDT, and software (E71013) listed in table 2. AOA also provided pricing information for the ophthalmology drill listed in this table, indicating a cost of $57. They expressed their appreciation for the recategorization and standardization of descriptions for equipment and supplies.

Response: We appreciate the documentation forwarded by these two organizations and have incorporated into the practice expense database the pricing information provided for the computer, VDT, and software. Because the ophthalmology drill is less than $500 (the standard established for equipment), we are removing it from the equipment list for the practice expense database.

Comment: The American Gastroenterological Association (AGA) expressed concern about the reduction in RVUs for CPT code 91065, a breath hydrogen test. They believe that the newer equipment listed in the practice expense database does not reflect the analyzer that is typically used, which is more expensive, and noted that the costs for the reagents have also increased.

Response: We are sympathetic to the concerns of the AGA regarding the typical equipment used for CPT code 91065 and would like to work with them to ascertain updated pricing information about the equipment most physicians utilize for this service. However, the majority of the decrease (76 percent) in practice expense RVUs for this procedure is due to the PEAC refinement for the clinical labor time that was reduced by nearly 50 percent.

Comment: The American Academy of Sleep Medicine indicated that most typical CPAP/BiPAP remote unit is a bilevel positive airway pressure unit and provided documentation for the price of this item.

Response: This price is reflected in the practice expense database.

Comment: The Society for Vascular Surgery (SVS), Society for Vascular Ultrasound and Society of Diagnostic Medical Sonography all expressed appreciation for the refinement to the inputs that apply to vascular ultrasound services. However, the commenters requested that we incorporate the requested refinements for the other ancillary equipment present in a vascular ultrasound room into other similar procedures. SVS specifically listed the following CPT codes: 93875–9 and 93990.

Response: In addition to the three new CPT codes for cerebrovascular arterial studies CPT 93890, 93892 and 93893, we have added the vascular ultrasound room to the codes indicated in the SVS comment noted above.

Comment: The American Psychiatric Association provided documentation for the cost of the ECT machine and the American Psychological Association provided information on the neurobehavioral status exam and testing, as well as the biofeedback equipment listed in table 2, along with the requested documentation.

Response: We appreciate this information. The practice expense database was revised to reflect this cost information.

Comment: The American Society of Clinical Oncology requested that the biohazard hood be substituted for the ventilator and hood blower as a practice expense input for the chemotherapy codes.

Response: We revised the database to reflect this change.

Comment: American Academy of Neurology supplied information and the necessary documentation on several equipment items listed in table 2 associated with neurology services.

Response: We have made the revisions to the prices for the ambulatory EEG recorder (E54008), ambulatory review station (E54009), and portable digital EEG monitor based on the documentation provided. Based on the documentation provided, we note that the price for the ambulatory review station was substantially reduced ($44,950 to $7,950).

Comment: The American Clinical Neurophysiology Society (ACNS) stated that the payment for CPT code 95819, an EEG service, was substantially reduced. The Society believes it is due to a price reduction for the EEG equipment (E54006) used in this service that was listed in Addendum D of the

proposed rule. The commenter indicated that the proposed price does not include the review station and software which is needed for this service and provided documentation for appropriately pricing this item.

Response: Based on the documentation provided, we have changed, on an interim basis for the 2005 fee schedule, the price for this item and note that this equipment price is associated only with CPT code 95819. We would be happy to work with ACNS in order to resolve any issues surrounding the RVUs for CPT code 95819. Reviewing the direct inputs for this code, we note that the largest contributor to the reduction of practice expense RVUs is the PEAC's refinement of this code's supply items.

Comment: The National Association for Medical Direction of Respiratory Care and the American College of Chest Physicians were in agreement with the proposed prices for equipment except for the pulse oximeter (including printer), E55003. The commenters referenced a price that is $83 more than that listed in the table, but provided no documentation.

Response: We appreciate the comments from these organizations regarding the repricing of the equipment items in the practice expense database. We have retained our price of $1,207 for the pulse oximeter and note that it is an average from two different available sources.

Comment: We received a comment from a consumer regarding the price of the electromagnetic therapy machine for HCPCS code G0329 with concerns about the low payment for this modality. While no documentation was submitted, the commenter noted that the cost for this equipment ranged from $25,000 to $35,000.

Response: We appreciate the commenter's remarks about the price of the electromagnetic therapy equipment, Diapulse. We have retained our price of $25,000 in the practice expense database because we do not have documentation that any higher-priced equipment is typically used. Similar to other modalities used in rehabilitation, including those used in wound care, we note that this procedure reflects comparable practice expense values.

Comment: Several specialty organizations questioned our substitution of the two standardized packs for previously PEAC-approved packs and trays, as discussed in our proposed rule. One specialty society suggested we consult with the AMA before proceeding on this point.

Response: We uniformly applied the PEAC-approved values for the packs and trays to all packs and trays, regardless of whether the codes had previously been refined by the PEAC. To the extent that a specialty society feels that it was disadvantaged by this policy, we would encourage them to bring the specific codes that should be excluded from this policy to the newly formed PERC (formerly PEAC) at the next RUC meeting in February 2005.

Comment: Several specialty organizations indicated that they were in the process of obtaining pricing information on equipment items and would provide it as soon as possible. One commenter also asked that we retain the items proposed for deletion as they are necessary in providing their services, but provided no documentation.

Response: In the proposed rule, we noted that we might eliminate those items from the database for which documented pricing information was not received. Due to the number of outstanding equipment prices, and the number of societies that are underway in their search for this data, we have decided to extend the submission deadline. We would encourage specialty societies to submit price information soon to help ensure that it can be used to establish practice expense RVUs in next year's proposed rule.

BILLING CODE 4120–01–P

Table 2

Equipment Items Needing Specialty Input for Pricing and Proposed Deletions

2005 Description	2004 Price	Primary specialties associated with item	*CPT code(s) associated with item	Prior status of equipment item	Commenter response	CMS action taken
ambulatory blood pressure monitor	3,000.00	cardiology	93784, 93786, 93788	See Note A	No/Insufficient documentation received	See Note D.
biofeedback equipment		psychology	90875	See Note A	Submitted price of $9,925	See Note F.
CAD processor unit (mammography)	210,000.00	radiology	76082, 76083, 76085	See Note A (Need system components)	No/Insufficient documentation received	See Note D.
camera system, cardiac, nuclear	675,000.00	anesthesia, IM, cardiology	78414	See Note A	Submitted price of $406,817	See Note F.
collimator, cardiofocal set	29,990.00	radiology	78206, 78607, 78647, 78803, 78807	See Note A	No/Insufficient documentation received	See Note D.
computer and VDT and software	9,000.00	ophthalmology, optometry	92060, 92065	See Notes A and C	Submitted price of $7,100	See Note F.
computer software, MR/PET/CT fusion	60,000.00	radiation oncology	77301	See Note A	Sumitted price of $60,000	See Note F.
computer system, record and verify	60,000.00	radiation oncology	77418	See Note A	Submitted prices from 2 sources, average of $163,593	See Note F.
computer workstation, 3D teletherapy treatment planning	221,500.00	radiation oncology	77300, 77305, 77310, 77315, 77321, 77331	See Note A	Submitted prices from 4 sources, average of $256,224	See Note F.
computer workstation, MRA post processing		radiology	71555, 72159, 72198, 73225, 73725, 74185	See Note A	No/Insufficient documentation received	See Note E.

2005 Description	2004 Price	Primary specialties associated with item	*CPT code(s) associated with item	Prior status of equipment item	Commenter response	CMS action taken
computer, server		radiation oncology	77301	See Note A (Need system components)	Submitted prices from 3 sources, average of $22,567	See Note F.
cortical bipolar-biphasic stimulating equipment		neurosurgery, neurology	95961, 95962	See Note A	No/Insufficient documentation received	See Note E.
CPAP/BiPAP remote clinical unit		pulmonary disease, neurology	95811	See Note A	Submitted price of $3,100	See Note F.
cryo-thermal unit		anesthesia	64620	See Notes A and C	No/Insufficient documentation received	See Note E.
densitometry unit, whole body, DPA	65,000.00	radiology	78351	See Notes A and C	No/Insufficient documentation received	See Note D.
densitometry unit, whole body, SPA	22,500.00	radiology	78350	See Notes A and C	No/Insufficient documentation received	See Note D.
Detector (Probe)	14,000.00	radiology, cardiology	78455	See Notes A and C	No/Insufficient documentation received	See Note D.
dialysis access flow monitor	10,000.00	nephrology	90940	See Note A	No/Insufficient documentation received	See Note D.
diathermy, microwave		anesthesia, GP, podiatry	97020	See Notes A and C	No/Insufficient documentation received	See Note D.
DNA image analyzer (ACIS)	200,000.00	lab, pathology	88358, 88361	See Note A	Submitted price of $195,000	See Note F.
drill, ophthalmology		ophthalmology	65125	See Note A	Submitted price of $57, less than $500	See Note G.
ECG signal averaging system	8,250.00	cardiology, IM	93278	See Note A	No/Insufficient documentation received	See Note D.
EEG monitor, digital, portable		neurology	95953	See Note A	Submitted price of $17,500	See Note F.
EEG recorder, ambulatory	6,940.00	neurology	95950	See Note A	Submitted price of $12,500	See Note F.
EEG review station, ambulatory	44,950.00	neurology	95950	See Note A	Submitted price of $7,950	See Note F.

2005 Description	2004 Price	Primary specialties associated with item	*CPT code(s) associated with item	Prior status of equipment item	Commenter response	CMS action taken
electroconvulsive therapy machine		psychiatry	90870	See Note A	Submitted price of $13,995	See Note F.
Electromagnetic therapy machine	25,000.00	physical therapy	G0329	See Note A	No/Insufficient documentation received	See Note D.
EMG botox	1,500.00	critical care, pulmonary, ophthalmology	92265	See Note A	No/Insufficient documentation received	See Note D.
fetal monitor software	35,000.00	ob-gyn, radiology	76818, 76819	See Note A	No/Insufficient documentation received	See Note D.
film alternator (motorized film viewbox)	27,500.00	radiology	329 codes	See Note B	No/Insufficient documentation received	See Note D.
generator, constant current	950.00	neurology, NP	95923	See Note A	No/Insufficient documentation received	See Note D.
HDR Afterload System, Nucletron - Oldelft	375,000.00	radiation oncology	77781-84	See Note A	Submitted prices from 2 sources, average of $375,9665	See Note F.
hyperbaric chamber	125,000.00	FP, IM, EM	99183	See Note A	No/Insufficient documentation received	See Note D.
hyperthermia system, ultrasound, external	360,000.00	radiation oncology	77600	See Note A	Submitted price of $360,000	See Note F.
hyperthermia system, ultrasound, intracavitary	250,000.00	radiation oncology	77620	See Note A	No/Insufficient documentation received	See Note D.
hysteroscopy ablation system	19,500.00	ob-gyn	58563	See Note A	No/Insufficient documentation received	See Note D.
image analyzer (CAS system)	92,000.00	pathology, neurology	88355, 88356	See Note A	No longer available	See Note H.
IMRT physics tools	55,485.00	radiation oncology	77301, 77418	See Note A	Submitted prices from 3 sources, average of $78,600	See Note F.
IVAC Injection Automatic Pump	2,500.00	radiology	78206, 78607, 78647, 78803, 78807	See Note A	No/Insufficient documentation received	See Note D.

2005 Description	2004 Price	Primary specialties associated with item	*CPT code(s) associated with item	Prior status of equipment item	Commenter response	CMS action taken
mammography reporting software		radiology	76090, 76091, 76092	See Note A	No/Insufficient documentation received	See Note E.
neurobehavioral status instrument-average	717.00	psychology, IM	96115, 96117	See Note A	Submitted price of $1,136.25	See Note F.
orthovoltage radiotherapy system	140,000.00	radiation oncology	77401	See Note A	No/Insufficient documentation received	See Note D.
OSHA ventilated hood	5,000.00	radiation oncology	77334	See Note B	No/Insufficient documentation received	See Note D.
plasma pheresis machine w/UV light source	37,900.00	radiology, dermatology	36481, 36510, 36522	See Note A	No/Insufficient documentation received	See Note D.
programmer, pacemaker	10,000.00	cardiology, cardiothoracic surgery, general surgery	33200-01, 33206-08, 33212-18, 33220, 33222, 33240, 33245-46, 33249, 33282	See Note A	Supplied without cost to physician offices, IDTFs, etc	See Note G.
pulse oxymetry recording software (prolonged monitoring)	3,660.00	pulmonary disease, IM	94762	See Note A	No/Insufficient documentation received	See Note D.
radiation treatment vault	550,670.00	radiation oncology	774XX	See Note B	Submitted prices from 3 sources, average $773,104	See Note F.
radiation virtual simulation system		radiation oncology	77280, 77285, 77290, 77402-16	See Note A	Submitted price of $967,000	See Note F.
remote monitoring service (neurodiagnostics)	9,500.00	neurology	95955	See Note A	No/Insufficient documentation received	See Note D.

2005 Description	2004 Price	Primary specialties associated with item	*CPT code(s) associated with item	Prior status of equipment item	Commenter response	CMS action taken
review master	23,500.00	pulmonary disease, neurology	95805, 95807-11, 95816, 95822, 95955-56	See Note A	No/Insufficient documentation received	See Note D.
room, basic radiology	150,000.00	radiology	103 codes	See Note A	No/Insufficient documentation received	See Note D.
room, mammography	130,000.00	radiology	19030, 19290-91, 19295, 76086-92, 76096	See Note A	No/Insufficient documentation received	See Note D.
room, radiographic-fluoroscopic	475,000.00		123 codes	See Note A	No/Insufficient documentation received	See Note D.
room, ultrasound, vascular		vascular		New-Added 10/04	Submitted price of $466,492	See Note F.
source, 10 Ci Ir 192	22,000.00	radiation oncology	77781-84	See Note A	Submitted prices from 2 sources, average $45,326	See Note F.
strontium-90 applicator	8,599.00	radiation oncology	77789	See Note A	Submitted prices from 3 sources, average $6,705	See Note F.
table, cystoscopy		urology	52204-24, 52265-75, 52310-17, 52327-32	See Note A	No/Insufficient documentation received	See Note E.
ultrasound color doppler, transducers and vaginal probe	155,000.00	ob-gyn	59070, 59074, 76818-19	See Note A	No/Insufficient documentation received	See Note D.
ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)	29,900.00	ob-gyn, cardiology, pediatrics	76825-28, 93303-12, 93314, 93320, 93325, 93350	See Note A	No/Insufficient documentation received	See Note D.
vacuum cart		anesthesia	64620	See Notes A and C	No/Insufficient documentation received	See Note E.

2005 Description	2004 Price	Primary specialties associated with item	*CPT code(s) associated with item	Prior status of equipment item	Commenter response	CMS action taken
video camera	1,000.00	radiation oncology	77418	See Note A	Submitted price of $1,000	See Note F.
water chiller (radiation treatment)	28,000.00	radiation oncology	77402-16	See Note B	Submitted prices from 2 sources, average $25,565	See Note F.
well counter		radiology	78160-72, 78282	See Note A	Submitted price of $3,450	See Note F.

Notes:
A. Additional information required. Need detailed description, source, and current pricing information.
B. Proposed deletion as indirect expense.
C. Item may no longer be available.
D. No/Insufficient documentation. Current price retained on an interim basis. Forward documentation promptly.
E. No/Insufficient documentation. No price in database. Forward documentation promptly.
F. Submitted price accepted.
G. Equipment deleted, per comment.
H. No longer available/marketed. Item deleted.

BILLING CODE 4120–01–C

d. Miscellaneous Practice Expense Issues

- Pricing for Seldinger Needle.

We proposed to average two prices of this supply item to reflect a cost of $5.175. We requested that, if commenters disagreed with this change in price, the comment should provide documentation to support the recommended price, as well as the specific type of needle that is most commonly used.

Comment: Commenters were in agreement with the proposed pricing of the seldinger needle.

Response: We will use the proposed price of $5.175 for this supply item in the practice expense database.

• Hysteroscopic Endometrial Ablation.

We proposed to assign, on an interim basis, the following direct practice expense inputs in the nonfacility setting for CPT code 58563, *Hysteroscopy, surgical; with endometrial ablation.* (**Note:** In the August 5, 2004 proposed rule this code was erroneously identified as 56853, which does not exist.) We also stated we would request that the RUC review these inputs as part of the practice expense refinement process.

+ *Clinical Staff:* RN/LPN/MTA—72 minutes (18 pre-service and 54 service)

+ *Supplies:* PEAC multispecialty visit supply package, pelvic exam package, irrigation tubing, sterile impervious gown, surgical cap, shoe cover, surgical mask with face shield, 3x3 sterile gauze (20), cotton tip applicator, cotton balls (4), irrigation 0.9 percent sodium chloride 500–1000 ml (3), maxi-pad, mini-pad, 3-pack betadine swab (4), Monsel's solution (10 ml), lidocaine jelly (1000 ml), disposable speculum, spinal needle, 18–24 g needle, 20 ml syringe, bupivicaine 0.25 percent (10 ml), 1 percent xylocaine (20 ml), cidex (10 ml), Polaroid film-type 667 (2), endosheath, and hysteroscopic ablation device kit.

+ *Equipment:* power table, fiberoptic exam light, endoscopic-rigid hysteroscope, endoscopy video system, and hysteroscopic ablation system.

Comment: Commenters, including many individual practitioners, were supportive of this proposed change. The specialty society also stated that they plan to present the inputs for this service at the RUC meeting in February 2005

Response: With the exception of the post incision care kit that we deleted because this procedure does not require an incision, we will finalize these inputs as proposed.

• Photopheresis.

We proposed to assign, on an interim basis, the following nonfacility practice expense inputs for the photopheresis service, CPT code 36522:

+ *Clinical Staff:* RN—223 minutes (treatment is for approximately 4 hours)

+ *Supplies:* multispecialty visit supply package, photopheresis procedural kit, blood filter (filter iv set), IV blood administration set, 0.9 percent irrigation sodium chloride 500–1000 ml (2), heparin 1,000 units-ml (10), povidone solution-betadine, methoxsalen (UVADEX) sterile solution-10 ml vial, 1 percent-2 percent lidocaine-xylocaine, paper surgical tape (12), 2x3 underpad (chux), nonsterile drapesheet 40 inches x 60 inches, nonsterile Kling bandage, bandage strip, 3x3 sterile gauze, 4x4 sterile gauze, alcohol swab pad (3), impervious staff gown, 19–25 g butterfly needle, 14–24g angiocatheter, 18–27 g needle, 20 ml syringe, 10–12 ml syringe, 1 ml syringe, 22–26 g syringe needle-3 ml.

+ *Equipment:* plasma pheresis machine with ultraviolet light source, medical recliner.

We also stated we would request that the RUC review these inputs.

Comment: One commenter supplied information on practice expense inputs for this code and indicated that an oncology nurse should be used, instead of an RN, to perform the procedure. A specialty society also stated that they would be providing information on this service at the September RUC meeting.

Response: We appreciate the information submitted by the commenters. This code was discussed at the September RUC meeting and recommended practice expense inputs for this service were provided to us. We do not agree with the RUC recommended clinical staff procedure (intra) time of 90 minutes. We believe that this time, which is half of the proposed intra time, does not accurately reflect the total time involved in performing this procedure. Our understanding is that the filtration rate and the procedures performed by the nurse for photopheresis are similar to those that are reflected in the selective apheresis services, CPT code 36516, with a PEAC-approved intra time of 240 minutes. Based on this, and the absence of specialty representation at the RUC familiar with the process, we are assigning 180 minutes for the intra time, as proposed. We are also assigning the RN/LPN staff type to this procedure, because we believe it is similar to other apheresis procedures. We will continue our examination of this issue and entertain ongoing dialog with all interested organizations and individuals, including the AMA and the RUC, the industry, and those physicians and individuals familiar with the photopheresis procedure in order to assure the accuracy of the intra time.

• Pricing of New Supply Items.

As part of last year's rulemaking process, we reviewed and updated the prices for supply items in our practice expense database. During subsequent meetings of both the PEAC and the RUC, supply items were added that were not included in the supply pricing update. The August 5, 2004 proposed rule included Table 3 Proposed Practice Expense Supply Item Additions for 2005, which listed supply items added as a result of PEAC or RUC recommendations subsequent to last year's update of the supply items and the proposed associated prices that we will use in the practice expense calculation.

We also identified certain supply items for which we were unable to verify the pricing information (*see* Table 4, Supply Items Needing Specialty Input for Pricing, in the August 5, 2004 proposed rule). We requested that commenters provide pricing information on these items along with documentation to support the recommended price. In addition, we also requested information on the specific contents of the listed kits, so that we do not duplicate any supply items.

Comment: Several commenters representing providers of these services stated that table 3 incorrectly associated ''gold markers'' with the brachtherapy intracavity codes. They were all in agreement that these markers are typically used in external beam treatments and payment is associated with unlisted procedure codes and should be paid for at cost.

Response: We have deleted the gold markers from CPT codes 77761–77763 and removed this supply from the practice expense database.

Comment: The American Urology Association noted that we should exclude the vasotomy kit from CPT codes 55200 and 55250.

Response: We have deleted the vasotomy kit from CPT codes 55200 and 55250.

Comment: The American College of Chest Physicians agreed with pricing of items used in their practices in table 3 and stated that the bronchogram tray does not need to be included in the practice expense database, as the procedure is seldom performed and, when it is, the procedure is performed in a facility.

Response: We have deleted the bronchogram tray from the practice expense database and corrected the direct inputs for CPT code 31708 accordingly.

Comment: We received comments from the American College of Cardiology (ACC) that included price quotes and names of sources for supply items listed on table 3.

Response: Unfortunately, ACC did not include the requested sufficient documentation, such as invoices or catalog web page links. We have asked ACC to forward this pricing documentation to us as soon as possible because it will be required for supplies to remain valued in the practice expense database. In the interim, for the 2005 fee schedule, we will maintain the prices currently in the practice expense database for the following supplies:

blood pressure recording form at $0.31, pressure bag (infuser) 500cc or 1000cc at $8.925, sterile, non-vented, tubing at $1.99.

Comment: Noting that a $15 supply item, needle-wire for localization of lesions in the breast (used preoperatively in CPT codes 19290 and 19291) was no longer used, a manufacturer requested that we replace this supply with an anchor-guide device valued at $245. The commenters also stated that this device is used in over 70 offices and imaging centers.

Response: We appreciate the comments from the manufacturer. However, during last year's rulemaking process we repriced all of our supplies, and the needle-wire price of $15 was an average of prices from two different sources ($17 and $13). This price was proposed and accepted by the medical specialty societies that we depend on to verify typical items in our practice expense database. We have retained the $15 needle-wire for localization because we believe it is typically used for this procedure.

The following table lists the items on which we requested input, the comments received, and the action taken.

BILLING CODE 4120–01–P

Table 3: Supplies Needing Specialty Input

2005 Description	Unit	Unit Price	Primary specialties associated with item	Prior status of item	Commenter response	CMS action taken
antibodies - detection	slide	30.90	lab, pathology	See Note A.	Deleted, CPEP refinement	See Note D.
blood pressure recording form, average	item	0.31	cardiology	See Note A.	No/Insufficient documentaion received	See Note B.
catheter, hyperthermia, closed-end	item		radiation oncology	See Note A.	Submitted price of $20	See Note C.
catheter, hyperthermia, open-end	item		radiation oncology	See Note A.	Submitted price of $20	See Note C.
Edrophonium	ml	4.67	gastroenterology	See Note A	No/Insufficient documentaion received	See Note B.
hysteroscope, ablation device	item	1,146.00	ob-gyn	See Note A	No/Insufficient documentaion received	See Note B.
kit, BCR/ABL DNA probe	kit	42.65	pathology	See Note A.	Submitted price of $42.65	See Note C.
kit, Her-2/Neu DNA probe	kit		pathology	New-Added 10/04	Submitted price of $105	See Note C.
kit, detection	slide	8.50	pathology, neurology	See Note A.	Refinement scheduled 2/05	See Note B.
kit, photopheresis procedure	kit	809.00	dermatology, ob-gyn	See Note A.	Submitted price of $858	See Note C.
kit, vasotomy	kit		urology	See Note A.	Delete, per comment	See Note D.
methoxsalen, sterile solution (UVADEX) 10 ml vial	ml	49.50	dermatology, radiation oncology	See Note A.	Submitted price of $49.50	See Note C.
pressure bag	item		cardiology	See Note A.	No/Insufficient documentaion received	See Note E.

2005 Description	Unit	Unit Price	Primary specialties associated with item	Prior status of item	Commenter response	CMS action taken
primary antibodies	slide	3.52	pathology, neurology	See Note A.	Refinement scheduled 2/05	See Note B.
tray, bronchogram	tray		pulmonary disease	See Note A.	Delete, per comment	See Note D.
tubing, sterile, non-vented (fluid administration)	item		cardiology	See Note A.	No/Insufficient documentaion received	See Note E.

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Notes:
A. Additional information required. Need detailed description (including kit contents), source, and current pricing information.
B. No/Insufficient documentation. Retained price in database, on interim basis. Forward documentation promptly.
C. Submitted price accepted.
D. Deleted per comment.
E. 2004 price retained on an interim basis. Forward documentation promptly.

BILLING CODE 4120–01–C

- Addition of Supply Item to CPT 88365, Tissue In Situ Hybridization.

We proposed to add, on an interim basis, a DNA probe to the CPEP database for CPT 88365, tissue in situ hybridization, with the understanding that the inclusion of the item would be subject to forthcoming RUC review.

Comment: Commenters were supportive of this proposal. The College of American Pathologists also encouraged us to include updated information on practice expense inputs from the September RUC meeting, while another commenter suggested that we run the information by the specialty society.

Response: The direct practice expense inputs for this code and two other codes in the same family were discussed at the September RUC after a presentation made by the specialty society. We have reviewed and accepted the RUC recommendations, and these practice expense inputs will be included in the practice expense database.

• Ophthalmology Equipment.

In cases where both the screening and exam lanes are included in the equipment list for the same ophthalmology service, we proposed to include only one lane because the patient could only be in one lane at a time. We proposed defaulting to the exam lane and, thus, we proposed deleting the screening lane from the practice expense inputs for these procedures. For the services where a lane change was made, time values were assigned to the exam lane in accordance with our established standard procedure.

Comment: The American Academy of Ophthalmology requested that we specifically identify the codes for which we deleted the screening lane, so that they can ensure that the correct lane was deleted.

Response: This information can be obtained by comparing the direct inputs in the practice expense database files for the 2004 and 2005 fee schedules that are posted on our Web site (*http://www.cms.hhs.gov/physicians/pfs*). However, we would be happy to work with the specialty organization to verify the accuracy of the information.

• Parathyroid Imaging, CPT code 78070.

Based on comments received from the RUC and the specialty society representing nuclear medicine, we proposed to crosswalk the charge-based RVUs from CPT 78306, *Bone and/or joint imaging; whole body,* to CPT 78070, *Parathyroid imaging.*

Comment: Several specialty societies expressed appreciation for this proposed change.

Response: We will finalize our proposal and crosswalk the charge-based RVUs from CPT code 78306 to CPT code 78070.

• Additional PE concerns.

Comment: We received information from the American Academy of Ophthalmology that two biometry devices (a-scan ultrasonic biometry unit and an optical coherence biometer) were listed as equipment for the ophthalmic biometry service, CPT code 92136. Only the optical coherence biometer should be included for this code.

Response: As requested by the specialty society, we have deleted the a-scan biometry unit from the equipment list for CPT code 92136.

Comment: We received comments from manufacturers, specialty societies representing renal physicians and vascular surgeons, and individual providers questioning the decrease in nonfacility practice expense RVUS for CPT code 36870, *Percutaneous thrombectomy, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis.* Some commenters believe this reduction occurred because the supplies listed in the database for this service reflect only one method of providing this service. While commenters acknowledged that the database includes the supplies used in approximately 50 percent of the instances this procedure is performed, the commenters claimed that other supplies may be used in the remaining occasions. Commenters requested that we add these other specific supplies to the database.

Response: Because there are a variety of supplies and equipment that can be used in performing a service, under the practice expense methodology, the supplies and equipment that are used in determining payment are those that are most typical for the procedure. Although there may be alternative supplies used, the inputs in the database reflect what is typically used (which is acknowledged by the commenters) and thus we are not adding the requested supplies to the practice expense database. However, we did note that the list of equipment did not reflect the cost of the angiography room that is used during the procedure, and this has been added to our database for this code.

Comment: Societies representing dermatologic specialties expressed concern about the reduction in practice expense RVUs for a photodynamic therapy service, CPT code 96567. The commenters believe that this reduction is due to the application of the dermatology scaling factor based on updated practice expense utilization and requested that this be reconsidered. These commenters also expressed appreciation that there is now a separate HCPCS code to bill for levulan that is needed for this procedure, but stated that there are two medical supplies that need to be included in the practice expense database: bacitracin, and a topical anesthetic cream.

Response: The practice expense RVUs for photodynamic therapy decreased only slightly in this year's proposed rule due to the proposed repricing of equipment. The decrease referred to by the commenter occurred after the first year that the code was established. At that time we obtained the utilization data that demonstrated that dermatologists performed the service and we then applied the same scaling factors to the code that we do for all dermatology services. Therefore, the scaling factor we now apply is correct. We will add the requested amount of bacitracin to the supply list for the code. Unfortunately, the topical anesthetic requested is not in our database and the commenters did not include pricing information so we are not able to include the item in our practice expense calculation.

Comment: A society representing interventional pain physicians expressed concern that the practice expense RVUs for CPT code 95990, *Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular)*, are understated when compared to the RVUs for CPT code 95991, the same service administered by a physician. According to the commenter, CPT code 95991 includes a total of 47 minutes of nonphysician labor and 37 minutes of physician labor or total professional time of 84 minutes. This is the total time spent with the patient before, during and after the refill. The commenter requested that the number of minutes of direct labor for CPT code 95990 should be a minimum of 84 minutes, since the nonphysician practitioner would be performing all the services associated with CPT code 95991 that are performed by both the physician and clinical staff. In addition, the commenter stated that CPT code 95990 should also be assigned physician work RVUs because there is physician oversight of the service even when performed by clinical staff. Two other commenters stated that both CPT codes 95990 and 95991 should be valued the same as the chemotherapy implanted pump refill service, CPT code 96530. The commenters state that this was the code originally used to report the above services, that CPT codes 95990 and 95991 originally were assigned higher RVUs than CPT code 96530 and that the MMA adjustments that increased the payment for CPT code 96530 should be applied to CPT codes 95990 and 95991.

Response: The commenter is correct that the clinical staff times for CPT codes 95990 and 95991 are the same (50 minutes of clinical staff time), although the clinical staff is performing the procedure in one case and assisting the physician in the other. However, the assumption underlying these times is that, in the cases where it is necessary for the physician to personally perform the procedure, the nurse is assisting for the entire time. If this assumption is not correct, then the clinical staff time for CPT code 95991 is overstated. Because CPT codes 95990 and 95991 are not considered drug administration codes under section 303 of the MMA, we will not apply the adjustments made for CPT code 96530 to these services. Therefore, we will not be revising the staff time for either code at this time, but would suggest that the RUC look further at this issue. We would also suggest that the society bring CPT code 95990 to the 5-year review, if they wish to make the case that work RVUs should be assigned.

Comment: The society representing interventional pain physicians questioned the ''professional component only'' designation we assigned to the codes for the analysis of an implanted intrathecal pump, CPT codes 62367 and 62368, and the subsequent low RVUs for these services. The commenter stated that if the payment is left as proposed, more physicians would stop offering intrathecal pumps to patients.

Response: This was an inadvertent error on our part that we have corrected for the final rule. These services are physicians' services that do not have separate professional and technical components. We thank the commenter for pointing out this error.

Comment: The Joint Council of Allergy, Asthma and Immunology expressed concern about the reduction in the proposed rule in practice expense RVUs for a number of allergy codes, in particular the venom therapy CPT codes, 95145 through 95149. The commenter stated that Medicare reimbursement for these services does not cover the physician's supply expense, due to the expensive venom antigens that are part of the service, and believes this is a result of the scaling factor being used.

Response: We are sympathetic to the commenter's concern about the high cost of the venom antigens and the specialty's low scaling factor. We would be happy to work with JCAAI further to see if a remedy can be identified regarding this subset of the allergy codes.

Comment: Two commenters stated that the practice expense RVUs for HCPCS code G0329, Electromagnetic Therapy for ulcers, were too low and supplied information on the supplies, equipment and clinical staff time for this service.

Response: Based on the information provided by the commenters, we added diapulse asetips and chux to the supplies in the practice expense database for this service. We also increased the equipment time to 30 minutes.

Comment: We received comments from the North American Spine Society (NASS) stating that the specific needle used for CPT codes 22520 and 22522, which was originally recommended by NASS, is the most expensive needle and may not be the most typical. The specialty noted that available needles range from $26 to $1,295, which represent the needle (termed vertebroplasty kit) in the practice expense database. NASS indicated that the specialties involved in performing these procedures are conducting a survey to determine the most commonly used needles and their costs.

Response: We appreciate the comments from NASS and look forward to receiving the survey results. In the interim, we have averaged the needle costs for the range indicated above by the specialty and have entered this figure, $660.50, as a placeholder for the 2005 fee schedule. Because of the large disparity between the lowest and highest needle costs, it is not reasonable to consider $660.50 as a true average cost for this supply item. We will continue to work with the specialty organizations in order to ensure that the 2006 fee schedule practice expense database reflects the value for the most typical needle used in these procedures.

Comment: We received comments from two medical societies with concerns about a decrease in practice expense RVUs for CPT code 95819, which is part of the EEG sleep study series of codes. These two organizations noted their willingness to bring this code to the February 2005 RUC meeting in order to rectify the direct practice expense inputs for this procedure.

Response: We have reviewed the family of EEG sleep-study codes and believe that a rank order anomaly exists relating primarily to the 2004 PEAC recommendation to delete the 25 reusable electrodes from CPT code 95819. We support and encourage these organizations to bring the entire EEG family of codes to the February 2005 RUC to ensure that this rank order anomaly can be resolved and the correct direct inputs can be identified for these procedures.

Comment: The Coalition for Advancement of Prosthetic Urology expressed concern about the continuing decline in practice expense RVUs for prosthetic urology procedures. They believe that this is due in part to the number of post service visits assigned to these services. They stated that information from a survey they conducted shows there are typically four to five post service visits rather than three as reflected in the database. The commenter also provided a copy of the survey information.

Response: The number of post service visits for these services was established based on recommendations from the RUC or by using the Harvard data. If they believe that the information regarding the number of post service visits for specific procedures is incorrect, the Coalition must request that the codes be examined as part of the 5-year refinement of work RVUs. An explanation of this process and the information that must be provided is found in section VI. of this rule.

B. Geographic Practice Cost Indices (GPCIs)

We are required by section 1848(e)(1)(A) of the Act to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components. While requiring that the practice expense and malpractice GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the physician work GPCIs reflect only one-quarter of the relative cost differences compared to the national average.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, to adjust the GPCIs at least every 3 years. This section of the Act also requires us to phase-in the adjustment over 2 years and to implement only one-half of any adjustment if more than 1 year has elapsed since the last GPCI revision. The GPCIs were first implemented in 1992. The first review and revision was implemented in 1995, the second review was implemented in 1998, and the third review was implemented in 2001. We reviewed and revised the malpractice GPCIs as part of the November 7, 2003 (68 FR 63196) physician fee schedule final rule. We were unable to revise the work and practice expense GPCIs at the time of the publication of the November 2003 final rule because the U.S. Census data, upon which the work and practice expense GPCIs are based, were not yet available.

In addition, section 412 of the MMA amended section 1848(e)(1) of the Act and established a floor of 1.0 for the work GPCI for any locality where the GPCI would otherwise fall below 1.0. This 1.0 work GPCI floor is used for purposes of payment for services furnished on or after January 1, 2004 and before January 1, 2007. Section 602 of the MMA further amended section 1848(e)(1) of the Act for purposes of payment for services furnished in Alaska under the physician fee schedule on or after January 1, 2004 and before January 1, 2006, and sets the work, practice expense, and malpractice expense GPCIs at 1.67 if any GPCI would otherwise be less than 1.67.

In the August 5, 2004 proposed rule, we proposed to revise the work and practice expense GPCIs for 2005 through 2007 based on updated U.S. Census data and Department of Housing and Urban Development (HUD) fair market rental (FMR) data. The same data sources and methodology used for the development of the 2001 through 2003 GPCIs were used for the proposed 2005 through 2007 work and practice expense GPCIs.

The relative respective weights for the 2004 work, practice expense and malpractice GPCIs, as well as the proposed 2005 through 2007 GPCI revisions, were derived using the same weights that were used in the Medicare Economic Index (MEI) revision discussed in the November 2003 physician fee schedule final rule (68 FR 63245).

1. Work Geographic Practice Cost Indices

As explained in the August 5, 2004 proposed rule, we used data from the 2000 decennial U.S. Census, by county, of seven professional occupations (architecture and engineering; computer, mathematical, and natural sciences; social scientists, social workers, lawyers; education, library, training; registered nurses; pharmacists; writers, artists, editors) in the development of the proposed work GPCIs. Physicians' wages are not included because Medicare payments are determinant of the physicians' earnings. Including physician wages in the physician work GPCI would, in effect, make the index dependent upon Medicare payments. Based on analysis performed by Health Economics Research, we believe that, in the majority of instances, the earnings of physicians will vary among areas to the same degree that the earnings of other professionals vary.

The U.S. Census Bureau has very specific criteria that tabulations must meet in order to be released to the public. To maximize the accuracy and availability of the data collection, the nonphysician professional wage data were aggregated by county and a median wage by county was calculated for each occupational category. These median wages were then weighted by the total RVUs associated with a given county to ultimately arrive at locality-specific work GPCIs. This geographic aggregation of Census data is the same methodology that was used in previous updates to the GPCIs.

The proposed work GPCIs reflected one-fourth of the relative cost differences, as required by statute, with the exception of those areas where MMA requires that the GPCI be set at no lower than 1.00 and that the Alaska GPCIs be set at 1.67.

2. Practice Expense GPCIs

As in the past, we proposed that the practice expense GPCI would be comprised of several factors that represent the major expenses incurred in operating a physician practice. The impact of each individual factor on the calculation of the practice expense GPCI is based on the relative weight for that factor consistent with the calculation of the MEI. The specific factors included:

- *Employee Wage Indices*—The employee wage index is based on special tabulations of 2000 Census data and is designed to capture the median wage by county of the professional labor force. The employee wage index uses the median wages of four labor categories that are most commonly present in a physician's private practice (administrative support, registered nurses, licensed practical nurses, and health technicians). Median wages for these occupations were aggregated by county in the same manner as the data for the work GPCI.
- *Office Rent Indices*—The HUD FMR data for the residential rents were again used as the proxy for physician office rents as they are in the current practice expense GPCIs. The proposed 2005 through 2007 practice expense GPCIs reflect the final fiscal year 2004 HUD FMR data. We believe that the FMR data remain the best available source for constructing the office rent index. The FMR data are available for all areas, are updated annually, and retain consistency from area-to-area and from year-to-year. A reduction in an area's rent index does not necessarily mean that rents have gone down in that area since the last GPCI update. Since the GPCIs measure area costs compared to the national average, a decrease in an area's rent index means that that area's rental costs are lower relative to the national average rental costs. Addendum X illustrates the changes in the rental index based upon the new FMR data.
- *Medical Equipment, Supplies, and other Miscellaneous Expenses*—The GPCIs assume that items such as medical equipment and supplies have a national market and that input prices do not vary among geographic areas. We were again unable to find any data sources that demonstrated price differences by geographic areas. As mentioned in previous updates, some price differences may exist, but these differences are more likely to be based on volume discounts rather than on geographic areas. The medical equipment, supplies, and miscellaneous expense portion of the practice expense geographic index will continue to be 1.000 for all areas in the proposed GPCIs, except for Alaska which will have an overall practice expense GPCI set at 1.67 for 2005 and 2006.

3. Fee Schedule Payments

All three of the indices for a specific fee schedule locality are based on the indices for the individual counties within the respective fee schedule localities. As in the past, fee schedule RVUs are again used to weight the county indices (to reflect volumes of services within counties) when mapping to fee schedule areas and in constructing the national average indices.

Fee schedule payments are the product of the RVUs, the GPCIs, and the conversion factor. Updating the GPCIs changes the relative position of fee schedule areas compared to the national average. Because the changes represented by the GPCIs could result in total payments either greater than or less than what would have been paid if the GPCIs were not updated, it is necessary to apply scaling factors to the proposed GPCIs to ensure budget neutrality (prior to applying the provisions of MMA that change the work GPCIs to a minimum of 1.0 and increase the Alaska GPCIs to 1.67 because these provisions are exempted from budget neutrality). We determined that the proposed work and practice expense GPCIs would have resulted in slightly higher total national payments. Because the law requires that each individual component of the fee schedule—work, practice expense, and malpractice expense—be separately adjusted by its respective GPCI, we proposed to scale each of the GPCIs separately. To ensure budget neutrality prior to applying the MMA provisions, we have made the following adjustments:

- Decreased the proposed work GPCI by 0.9965;

• Decreased the proposed practice expense GPCI by 0.9930; and

• Increased the malpractice GPCIs that were published in the November 7, 2003 final rule by 1.0021.

Because all geographic payment areas will receive the same percentage adjustments, the adjustments do not change the new relative positions among areas indicated by the proposed GPCIs. After the appropriate scaling factors are applied, the MMA provision setting a 1.0 floor has been applied to all work GPCIs falling below 1.0. Additionally, the GPCIs for Alaska have been set to 1.67 in accordance with MMA.

Comment: A specialty society representing family physicians recommended that we work with the Congress to eliminate the GPCIs or set them all at 1.00. The society stated that they understand the statutory requirement to apply the GPCIs, but that all geographic adjustment factors should be eliminated from the physician fee schedule, except for those designed to achieve a specific policy good, such as adjustment to encourage physicians to practice in underserved areas. The commenter contended that elimination of the GPCIs would have a positive effect on the availability of medical care to rural beneficiaries. Other commenters suggested that we should no longer apply the work GPCI to the work RVUs.

We also received numerous comments on the subject of the source of the data we use in the development of the GPCIs. Commenters suggested that we find data sources other than Census Bureau data. They believe the census data become obsolete very quickly and want us to use data that reflect up-to-date prices for inputs. This would, they argue, make the GPCI values more realistic.

A medical specialty group commented that the index is flawed because—

• It is based on the tenuous assumption that the relative differences in the prices of the input proxies accurately reflect relative changes in prices of corresponding physician practice cost components; and,

• It applies uniform weights to practice cost components, despite evidence of geographic variation in component shares.

Several commenters had specific concerns about the proxies used for the work and practice expense GPCIs, for example—

• Using data for four employee classes to measure relative compensation differences for all physicians' office staff which does not reflect the changes in medical practice that have occurred since the index was developed;

• Using residential real estate prices to reflect relative differences in physicians' office costs; and

• Using nationally uniform prices for supplies, equipment, and other expenses.

Another particular concern among commenters is the use of HUD apartment rental data as the source of costs for physicians' rents. Instead, they argue, we should find, or carry out, a national study of retail and business rents.

Another commenter asserts that these indices have not been verified by peer-reviewed published research since they were instituted and that we should replace the indices with data from nationwide studies that validate and update actual cost of practice data.

Response: As noted by a commenter, we are required by the Congress to adjust for geographic differences in the operational cost of physicians' practices by applying geographic price indices to each component of the Physician Fee Schedule. However, we also believe it appropriate in our resource based payment system to account for real differences in physicians' costs in different geographical areas. We share the concern about access to care for our rural beneficiaries and, in this rule, we are finalizing our proposals on payment adjustments to physicians in underserved areas through the HPSA Incentive Payment Program. For the commenters who object to the GPCI adjustment to the work RVUs, we would note that for 2005 and 2006 the floor for the work GPCI will be 1.00.

With reference to the issue of the GPCI data source, we are always open to suggestions about possible data sources; however, we believe the most reliable source of national, comparable data at the county level is the Census Bureau. Other data sources that we have examined either fail to produce the data at the county level, cannot be compared nationally, or offer no means of comparability over time.

We believe that the proxies, while not perfect, are the best tools available for the development of the GPCIs. For example, if we were to eliminate all proxies, we would have to collect actual physicians' office data from a sufficiently large sample in each locality to calculate the GPCIs. This would place a substantial burden on the office staff and would be prohibitively expensive. Also, the benefits from that approach would be uncertain.

The question of applying uniform weights to practice components is an area where more research could lead to better information about the variation attributable to case mix and the availability of other health resources, input prices, and practice styles. However, it is important to note that much of the variation associated with case and specialty mix is accounted for by the varying RVUs for different services. However, we are open to exploring this issue.

On the issue of which employee categories are included in the employee wage index component of the practice expense GPCI calculation, we included those that have been determined in the past to be most commonly present in a physician's private practice. We are considering the suggestion that we include a broader group of employment categories in the future.

While we recognize that apartment rents are not a perfect proxy for physician office rents, there are no existing national studies that present reliable retail and business rentals data. We would welcome any nationally consistent data that could be used for this purpose.

We noted in the proposed rule that we were unable to find any data sources that demonstrate price differences by geographic areas for medical equipment and supplies. Once again, however, we welcome any nationally consistent data for this purpose.

We appreciate the concern expressed by the commenter who suggested our GPCI methodology has not been subjected to peer-review validation since its inception, but we are not aware of any currently available data that could replace our methodology. Furthermore, we believe the process of updating the GPCIs periodically through notice and comment rulemaking affords an opportunity for a thorough review of the GPCI calculation methodology.

Comment: A member of a medical society suggested that we make the floor of 1.00 permanent for the work GPCI and incrementally increase both the practice expense GPCI and the professional liability insurance GPCI to 1.00 over the next ten years.

Response: We have no authority to extend the floor of the work GPCI, or to create a 1.00 floor for the practice expense and professional liability insurance GPCIs. Section 1848(c)(1)(A) of the Act requires that the index reflect resource costs relative to the national average, indicating that, aside from the MMA provision establishing a floor on the work GPCI through 2006, localities with costs below the national average have GPCIs below 1.00.

Comment: A specialty organization representing the long term care industry suggested that we phase in the new

GPCI values over a three-year period to minimize the impact of the changes.

Response: We are required by section 1848(e)(1)(C) of the Act to review and adjust the GPCIs every 3 years. This section of the Act also requires us to phase in the adjustment over 2 years and implement only one-half of any adjustment if more than 1 year has elapsed since the last GPCI revision. We believe this phase-in appropriately balances any negative impacts of the changes with the positive impacts on those localities where the GPCIs increase.

4. Payment Localities

As discussed in the August 5, 2004 proposed rule, we have considered, and are continuing to examine, alternatives to the composition of the current 89 Medicare physician payment localities to which the GPCIs are applied.

While we have considered alternatives, we have been unable to establish a policy and criteria that would satisfactorily apply to all situations. Any policy that we would propose would have to apply to all States and payment localities. If, for example, we were to establish a policy that when adjacent county geographic indices exceeded a threshold amount the lower county could be moved to the higher county or that a separate locality could be created, redistributions would be caused within a State.

Because there will be both winners and losers in any locality reconfiguration, the State medical associations should be the impetus behind these changes. The support of State medical associations has been the basis for previous changes to statewide areas, and continues to be equally important in our consideration of other future locality changes.

Comment: We received numerous comments from physicians and individuals, including members of the Congress, living in and around Santa Cruz County, California. Their comments uniformly expressed the opinion that Santa Cruz be taken out of the ''Rest of California'' payment locality and placed in a separate payment locality.

Additionally, the California Medical Association (CMA) submitted a ''placeholder'' proposal to move any county with a county-specific geographic adjustment factor (GAF) that is 5 percent greater than its locality GAF to its own individual county payment locality. Under their proposal, any reductions in payments to maintain budget neutrality in light of the higher payments to physicians in the counties that are moved into the new independent county localities would be divided equally among all payment localities within the State of California. Additionally, for 2005 and 2006, the GAFs in localities from which the high-cost counties are removed would not be reduced as a result of removing the counties.

Response: We greatly appreciate the efforts of the CMA and many others toward addressing this difficult issue. We also recognize the concerns expressed by the residents of Santa Cruz County about the impact of the current payment disparities upon physicians in their community. Our consistent position has been that we will be responsive to requests for locality changes when there is a demonstrated consensus within the State medical association for the change. Due to the re-distributive impacts of these types of changes, we believe this approach helps ensure the appropriateness of any such change.

We are required, however, to publish the final 2005 GPCIs and GAFs in this rule, and we have applied the current definitions for all California localities.

On October 21, 2004, the CMA Board of Trustees voted without objection to support the placeholder proposal submitted in the CMA's comment with the amendment to limit the time period to the years 2005 through 2006. However, we have determined that we do not have the authority under section 1848(e) of the Act to reduce the GPCIs of some localities in a State to offset higher payments to other localities. Nonetheless, we are eager to work with CMA and its Congressional Representatives to resolve this difficult problem as quickly and fairly as possible.

Comment: We received comments from physicians, individuals and the Texas Medical Association regarding locality payments. These commenters request that we regard all counties in a metropolitan statistical area (MSA) as being in a single payment locality. This would, they argue, equalize payments in those areas where growth has expanded city boundaries across county lines.

Response: As noted above, we will be responsive to requests for locality changes when there is a demonstrated consensus within the State medical association for the change.

Result of Evaluation of Comments

We will finalize the GPCIs as proposed.

C. Malpractice Relative Value Units (RVUs)

1. Proposed Methodology for the Revision of Resource-based Malpractice RVUs

The methodology used in calculating the proposed resource-based malpractice RVUs is the same methodology that was used in the initial development of resource-based RVUs, the only difference being the use of more current data. The proposed resource-based malpractice expense RVUs are based upon:

- Actual 2001 and 2002 malpractice premium data;
- Projected 2003 premium data; and
- 2003 Medicare payment data on allowed services and charges.

As in the initial development of resource-based malpractice expense RVUs in the November 2, 1999 final rule, we proposed to revise resource-based malpractice expense RVUs using specialty-specific malpractice premium data because they represent the actual malpractice expense to the physician. In addition, malpractice premium data are widely available. We proposed using actual 2001 and 2002 malpractice premium data and projected 2003 malpractice premium data for three reasons:

- These are the most current national claims-made premium data available.
- These data capture the highly publicized and most recent trends in the specialty-specific costs of professional liability insurance.
- These are the same malpractice premium data that were used in the development of revised malpractice GPCIs in the November 7, 2003 final rule.

We were unable to obtain a nationally representative sample of 2003 malpractice premium data for the following two reasons:

- The premium data that we collected from the private insurance companies had to ''match'' the market share data that were provided by the respective State Departments of Insurance (DOI). Because none of the State DOI had 2003 market share information at the time of this data collection, 2003 premium data were not usable; and
- The majority of private insurers were not amenable to releasing premium data to us. In the majority of instances, the private insurance companies would release their premium data only to the State Department of Insurance.

Discussions with the industry led us to conclude that the primary determinants of malpractice liability costs remain physician specialty, level

of surgical involvement, and the physician's malpractice history. Malpractice premium data were collected for the top 20 Medicare physician specialties measured by total payments. Premiums were for a $1 million/$3 million mature claims-made policy (a policy covering claims made, rather than services provided during the policy term). We attempted to collect premium data from all 50 States, Washington, DC, and Puerto Rico. Data were collected from commercial and physician-owned insurers and from joint underwriting associations (JUAs). A JUA is a State government-administered risk pooling insurance arrangement in areas where commercial insurers have left the market. Adjustments were made to reflect mandatory patient compensation funds (PCFs) (funds to pay for any claim beyond the statutory amount, thereby limiting an individual physician's liability in cases of a large suit) surcharges in States where PCF participation is mandatory. The premium data collected represent at least 50 percent of physician malpractice premiums paid in each State.

For 2001, we collected premium data from 48 States (for purposes of this discussion, State counts include Washington, DC and Puerto Rico). We were unable to obtain premium data from Kentucky, New Hampshire, New Mexico, and Washington, DC. To calculate a proxy for the malpractice premium data for these four areas in 2001, we began with the most current malpractice premium data collected for these areas, 1996 through 1998 (the last premium data collection that was undertaken). We calculated an average premium price (using 1996 through 1998 data) for all States except Kentucky, New Hampshire, New Mexico, and Washington, DC. Similarly, we calculated an average premium price for the 1999 through 2001 period for all States except Kentucky, New Hampshire, New Mexico, and Washington, DC. We calculated the percentage change in these premium prices as the percent difference between the 1999 to 2001 calculated average premium price and the 1996 to 1998 calculated average premium price. We then applied this percentage change to the weighted average 1996 to 1998 malpractice premium price for these four areas to arrive at a comparable 1999 to 2001 average premium price.

For 2002, we were able to obtain malpractice premium data from 33 States. Many State Departments of Insurance had not yet obtained premium data from the primary insurers within their States at the time of this data collection. For those States for which we were unable to obtain malpractice premium data, we calculated a national average rate of growth for 2002 and applied this national rate of growth to the weighted average premium for 2001 to obtain an average premium for 2002 for each county for which we were unable to obtain malpractice premium data for 2002.

We projected premium values for 2003 based on the average of historical year-to-year changes for each locality (when locality level data were available) or by State (when only statewide premium data projections were available). First, we calculated the percentage changes in the premiums from the 1999 through 2000, 2000 through 2001, and 2001 through 2002 periods for each payment locality. Next, we calculated the geometric mean of these three percentages and applied the mean to the 2002 premium to obtain the forecasted 2003 malpractice premium. We used the geometric mean to calculate the forecasted 2003 premium data because the geometric mean is commonly used to derive the mean of a series of values that represent rates of change. Because the geometric mean is based on the logarithmic scale, it is less impacted by outlying data. Alternative methods, such as linear extrapolation tended to yield more extreme values that were the result of outlying data.

Malpractice insurers generally use five-digit codes developed by the Insurance Services Office (ISO), an advisory body serving property and casualty insurers, to classify physician specialties into different risk classes for premium rating purposes. ISO codes classify physicians not only by specialty, but in many cases also by whether or not the specialty performs surgical procedures. A given specialty could thus have two ISO codes, one for use in rating a member of that specialty who performs surgical procedures and another for rating a member who does not perform surgery. We use our own system of specialty classification for payment and data purposes. It was therefore necessary to map Medicare specialties to ISO codes and insurer risk classes. Different insurers, while using ISO codes, have their own risk class categories. To ensure consistency, we used the risk classes of St. Paul Companies, one of the oldest and largest malpractice insurers. Although St. Paul Companies have recently terminated writing professional liability insurance policies at the time of this data collection they were still the largest and most nationally representative writer of professional liability insurance policies in the nation. The crosswalks for Medicare specialties to ISO codes and to the St. Paul risk classes used are reflected in Table 4.

Some physician specialties, nonphysician practitioners, and other entities (for example, independent diagnostic testing facilities) paid under the physician fee schedule could not be assigned an ISO code. We crosswalked these specialties to similar physician specialties and assigned an ISO code and a risk class. These crosswalks are reflected in Table 5.

In the development of the proposed resource-based malpractice RVU methodology, we considered two malpractice premium-based alternatives for resource-based malpractice RVUs: the dominant specialty approach and the specialty-weighted approach.

Dominant Specialty Approach

The dominant specialty approach bases the malpractice RVUs upon the risk factor of only the dominant specialty performing a given service as long as the dominant specialty accounted for at least 51 percent of the total utilization for a given service. When 51 percent of the total utilization does not comprise the dominant specialty, this approach uses a modified specialty-weighted approach. In this modified specialty-weighted approach, two or more specialties are collectively defined as the dominant specialty. Starting with the specialty with the largest percentage of allowed services, the modified specialty-weighted approach successively adds the next highest specialty in terms of percentage of allowed services until a 50 percent threshold is achieved. The next step is to sum the risk factors of those specialties (weighted by utilization) in order to achieve at least 50 percent of the total utilization of a given service and then to use the factors in the calculation of the final malpractice RVU.

The dominant specialty approach produces modest increases for some specialties and modest decreases for other specialties. The largest increase for any given specialty, over the specialty-weighted approach, is less than 1.5 percent of total RVUs, while the largest decrease for any given specialty is less than 0.5 percent of total RVUs. The dominant specialty approach also fails to account for as much as 49 percent of the utilization associated with a given procedure.

Specialty-Weighted Approach

The approach that we adopted in the November 1999 final rule and proposed

to use for 2005 bases the final malpractice RVUs upon a weighted average of the risk factors of all specialties performing a given service. The specialty-weighted approach ensures that all specialties performing a given service are accounted for in the calculation of the final malpractice RVU. Under the proposed methodology, we—

• *Compute a national average premium for each specialty.* Insurance rating area malpractice premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by the total county RVUs (as defined by Medicare claims data), which were divided by the malpractice GPCI applicable to each county to standardize the relative values for geographic variations. If the malpractice RVUs were not normalized for geographic variation, the locality cost differences (as reflected by the GPCIs) would be counted twice. The product of the malpractice premiums and standardized RVUs is then summed across specialties for each county. This calculation is then divided by the total RVUs for all counties, for each specialty, to yield a national average premium for each specialty. As stated previously, we used an average of the 3 most current years, 2001 to projected 2003 malpractice premiums, in our calculation of the proposed malpractice RVUs. See Table 6 for a display of the average premiums for the top 20 Medicare specialties;

• *Calculate a risk factor for each specialty.* Differences among specialties in malpractice premiums are a direct reflection of the malpractice risk associated with the services performed by a given specialty. The relative differences in national average premiums between various specialties can be expressed as a specialty risk factor. These risk factors are an index calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest average premium, nephrology. The risk factors used in the development of the resource-based malpractice RVUs are displayed in Table 7;

• *Calculate malpractice RVUs for each code.* Resource-based malpractice RVUs were calculated for each procedure. In order to calculate malpractice RVUs for each code, we identified the percentage of services performed by each specialty for each respective procedure code. This percentage was then multiplied by each respective specialty's risk factor as calculated in Step 2. The products for all specialties for the procedure were then summed, yielding a specialty-weighted malpractice RVU reflecting the weighted malpractice costs across all specialties for that procedure. This number was then multiplied by the procedure's work RVUs to account for differences in risk-of-service. Since we were unable to find an acceptable source of data to be used in determining risk-of-service, work RVUs were used. We welcome any suggestions at any time for alternative data sources to be used in determining risk-of-service.

Certain specialties may have more than one ISO rating class and risk factor. The surgical risk factor for a specialty was used for surgical services and the nonsurgical risk factor for evaluation and management services. Also, for obstetrics/gynecology, the lower gynecology risk factor was used for all codes except those obviously surgical services, in which case the higher, surgical risk factor was used.

Certain codes have no physician work RVUs. The overwhelming majority of these codes are the technical components (TCs) of diagnostic tests, such as x-rays and cardiac catheterization, which have a distinctly separate technical component (the taking of an x-ray by a technician) and professional component (the interpretation of the x-ray by a physician). Examples of other codes with no work RVUs are audiology tests and injections. Nonphysicians, in this example, audiologists and nurses, respectively, usually furnish these services. In many cases, the nonphysician or entity furnishing the TC is distinct and separate from the physician ordering and interpreting the test. We believe it is appropriate for the malpractice RVUs assigned to TCs to be based on the malpractice costs of the nonphysician or entity, not the professional liability of the physician.

Our proposed methodology, however, would result in zero malpractice RVUs for codes with no physician work, since we proposed the use of physician work RVUs to adjust for risk-of-service. We believe that zero malpractice RVUs would be inappropriate because nonphysician health practitioners and entities such as independent diagnostic testing facilities (IDTFs) also have malpractice liability and carry malpractice insurance. Therefore, we proposed to retain the current charge-based malpractice RVUs for all services with zero work RVUs. We also solicited comments and suggestions for constructing resource-based malpractice RVUs for codes with no physician work.

• *Rescale for budget neutrality.* The law requires that changes to fee schedule RVUs be budget neutral. The current resource-based malpractice RVUs and the proposed resource-based malpractice RVUs were constructed using entirely different malpractice premium data. Thus, the last step in this process is to adjust for budget neutrality by rescaling the proposed malpractice RVUs so that the total proposed resource-based malpractice RVUs equal the total current resource-based malpractice RVUs. The proposed resource-based malpractice RVUs for each procedure were then multiplied by the frequency count for that procedure to determine the total resource-based malpractice RVUs for each procedure. The total resource-based malpractice RVUs for each procedure were summed for all procedures to determine the total fee schedule proposed resource-based malpractice RVUs. The total fee schedule *proposed* resource-based malpractice RVUs were compared to the total *current* resource-based malpractice RVUs. The total current and proposed malpractice RVUs were equal and, therefore, budget neutral. Thus, no adjustments were needed to ensure that expenditures remained constant for the malpractice RVU portion of the physician fee schedule payment.

The proposed resource-based malpractice RVUs were shown in Addendum B of the August 5, 2004 proposed rule. The values did not reflect any final budget-neutrality adjustment, which we stated would be made in the final rule based upon the more current Medicare claims data. The malpractice RVUs identified in this final rule did not require the application of a scaling factor to retain budget neutrality.

Because of the differences in the sizes of the three fee schedule components, the implementation of the updated resource-based malpractice RVUs has a smaller payment effect than the previous implementation of resource-based practice expense RVUs. On average, work represents about 52.5 percent of the total payment for a procedure, practice expense about 43.6 percent of the total payment, and malpractice expense about 3.9 percent of the total payment. Thus, a 20 percent change in practice expense or work RVUs would yield a change in payment of about 8 to 11 percent. In contrast, a corresponding 20 percent change in malpractice values would yield a change in payment of only about 0.6 percent.

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TABLE 4:

Medicare Code	Medicare Description	ISO code		Risk Class		St. Paul's Description
		Surgery	Other	Surgery	Other	
1	General practice	80117	80420	4	1	Family/Gen. Practitioners - No Obstetrical
2	General surgery	80143	80143	5	5	Surgery General
3	Allergy/Immunology	80254	80254	1A	1A	Allergy
4	Otolaryngology	80159	80265	3	1	Otarhinolaryngology
5	Anesthesiology	80151	80151	5A	5A	Anesthesiology
6	Cardiology	80281	80255	2	1	Cardiovascular Disease
7	Dermatology	80472	80256	5	1A	Dermatology
8	Family practice	80117	80420	4	1	Family/Gen. Practitioners - No Obstetrical
10	Gastroenterology	80104	80241	3	1	Gastroenterology
11	Internal medicine	80284	80257	2	1	Internal medicine
13	Neurology	80288	80261	2	2	Neurology
14	Neurosurgery	80152	80152	8	8	Surgery Neurology
16	Obstetrics/Gynecology	80167	80244	4	1	Gynecology
18	Ophthalmology	80114	80263	2	1	Ophthalmology
20	Orthopedic surgery	80501	80501	5	5	Surgery Orthopedic - excluding Spinal Surgery
20	Orthopedic surgery	80154	80154	6	6	Surgery Orthopedic - including Spinal Surgery
22	Pathology	80292	80266	2	1A	Pathology
24	Plastic and reconstructive surgery	80156	80156	5	5	Surgery Plastic
25	Physical medicine and rehab	80235	80235	1	1	Physical medicine and rehab
26	Psychiatry *	80492, 80431	80249	2	1A	Psychiatry
28	Colorectal surgery	80115	80115	3	3	Surgery Colon and Rectal
29	Pulmonary Disease	80269	80269	1	1	Pulmonary Disease
30	Diagnostic radiology **	80280	80253	2	2	Radiology
33	Thoracic surgery	80144	80144	6	6	Surgery Thoracic
34	Urology	80145	80145	2	2	Surgery Urological
36	Nuclear medicine	80262	80262	1	1	Nuclear medicine

Medicare Code	Medicare Description	ISO code		Risk Class		St. Paul's Description
		Surgery	Other	Surgery	Other	
37	Pediatric medicine	80293	80267	2	1	Pediatrics
38	Geriatric medicine ***	80276	80243	2	1	Geriatrics
39	Nephrology ***	80287	80260	2	1	Nephrology
40	Hand surgery	80169	80169	5	5	Surgery Hand
44	Infectious disease	80279	80246	2	1	Infectious disease
46	Endocrinology ***	80272	80238	2	1	Endocrinology
65	Physical therapist (independent)	80235	80235	1	1	Physical medicine and rehab
66	Rheumatology	80252	80252	1	1	Rheumatology
67	Occupational therapist (independent)	80235	80235	1	1	Occupational Medicine
77	Vascular surgery	80146	80146	6	6	Surgery Vascular
78	Cardiac surgery	80141	80141	6	6	Surgery Cardiac
82	Hematology	80278	80245	2	1	Hematology
83	Hematology/oncology	80473	80473	1	1	Oncology
84	Preventive medicine	80231	80231	1	1	General Preventive Medicine
92	Radiation Oncology ****	80425	80425	2	2	Radiation Therapy
93	Emergency medicine	80157	80102	5	4	Emergency Medicine
98	Gynecologist/oncologist	80167	80244	4	1	Gynecology

Note: For specialties with multiple risk classifications depending on the level of surgical involvement, the highest level of surgery for each specialty was selected for the "surgery" ISO and risk class; and the lowest level of surgery was selected for the "nonsurgery" ISO and risk class.

Note: If a specialty has only one risk classification the same classification was used for both surgery and nonsurgery..*The ISO codes for surgery for Psychiatry represents Psychiatry - shock therapy.

**St. Paul's is the only one of the five companies that has a "major invasive" procedures ISO Code for Radiology; therefore, the "minor invasive procedures" ISO Code is being used as the highest level of surgery.

***St. Paul's is the only one of the five companies that has a "major surgery" ISO Code for Geriatrics, Nephrology, and Endocrinology; therefore, the minor Surgery" ISO Code is being used as the highest level of surgery.

****Medical Protective's Description was used as St. Paul's does not provide specific medical malpractice insurance for Radiation Therapy.

TABLE 5:

Medicare Code	Unassigned Medicare Specialty	Crosswalk Specialty
12	Osteopathic Manipulative Therapy	Family Practice
32	Anesthesiologist Assistant	Anesthesiology
35	Chiropractic	Physical medicine and rehab
41	Optometry	Ophthalmology
43	Certified Registered Nurse Assistant	All Physicians
47	Physiological Laboratory (independent)	All Physicians
48	Podiatry	All Physicians
50	Nurse Practitioner	All Physicians
62	Psychologist	Psychiatry
68	Clinical Psychologist	Psychiatry
69	Clinical Laboratory	All Physicians
70	Multi-Specialty Clinic or Group Practice	All Physicians
74	Radiation Therpay Center	Radiation Oncology
76	Peripheral Vascular Disease	Vascular Surgery
79	Addiction Medicine	Psychiatry
80	Licensed Clinical Social Worker	Psychiatry
81	Critical Care (Intensivists)	All Physicians
85	Maxillofacial Surgery	Plastic Surgery
86	Neuropsychiatry	Psychiatry
89	Certified Clinical Nurse Specialist	All Physicians
90	Medical Oncology	Internal Medicine
91	Surgical Oncology	General Surgery
94	Interventional Radiology	Radiology
96	Optician	Ophthalmology
97	Physician Assistant	All Physicians

TABLE 6:

ISO	Specialty	2001 Average	2002 Average	2003 Average	1996-1998 Average	2001-2003 Average[1]	Annual Trend[2]	Specialty MGPCI[3]	Normalized 2001-2003 Premium[4]	Risk Factor[5]
80269	Pulmonary disease	12,574	13,456	14,541	9,508	13,524	7.30%	1.027	13,168	2.14
80280	Diagnostic radiology	15,807	16,783	17,997	12,372	16,862	6.39%	0.997	16,913	2.75
80284	Internal medicine	14,395	15,714	16,985	11,836	15,698	5.81%	1.028	15,270	2.48
80274	Gastroenterology	14,347	15,398	16,643	11,745	15,463	5.65%	1.017	15,204	2.47
80143	General surgery	33,163	36,004	39,059	27,825	36,075	5.33%	0.957	37,696	6.13
80423	General practice	13,325	14,479	15,731	11,234	14,512	5.25%	0.943	15,389	2.50
80288	Neurology	16,206	17,330	18,629	13,726	17,388	4.84%	1.032	16,849	2.74
80114	Ophthalmology	13,064	14,103	15,317	11,209	14,161	4.79%	0.997	14,204	2.31
80152	Neurosurgery	64,724	70,125	76,060	57,701	70,303	4.03%	0.952	73,848	12.00
80281	Cardiology	14,798	15,836	17,085	13,204	15,906	3.79%	1.021	15,579	2.53
80145	Urology	18,701	20,253	21,931	16,958	20,295	3.66%	0.999	20,315	3.30
80159	Otolaryngology	21,720	23,127	24,794	19,990	23,214	3.04%	0.997	23,284	3.78
80154	Orthopedic w/ spinal	40,384	43,758	47,321	38,584	43,821	2.58%	0.955	45,886	7.46
80144	Thoracic surgery	39,538	43,200	47,249	38,812	43,329	2.23%	1.020	42,479	6.91
80282	Dermatology	11,046	11,549	12,375	10,650	11,657	1.82%	1.020	11,428	1.86
80260	Nephrology [6]	8,408	9,290	10,142	n/a	9,280	n/a	0.999	9,289	1.51
80146	Vascular surgery	39,391	42,660	46,211	n/a	42,754	n/a	1.014	42,164	6.85
80141	Cardiac surgery	37,802	40,498	43,722	n/a	40,674	n/a	0.921	44,163	7.18
80425	Radiation oncology	13,800	14,755	15,976	n/a	14,844	n/a	0.995	14,918	2.43
80102	Emergency medicine	20,671	22,672	24,733	n/a	22,692	n/a	0.974	23,298	3.79

[1] A simple average of figures for 2001, 2002, and 2003.
[2] Annualized average growth rate between 1996 - 1998 and 2001 - 2003.

[3] An average of locality malpractice GPCIs using specialty-specific malpractice RVUs as weights.
[4] 2001 - 2003 premium divided by specialty MGPCI.
[5] (Normalized 2001 - 2003 Premium, .9289) x 1.51.
[6] Nephrology is set to 1.51 to be consistent with the risk factor taken from the rating manuals.
n/a siginifies that the premium data was not available.

TABLE 7:

Medicare Code	Medicare Description	Nonsurgical Risk Factor	Surgical Risk Factor
01	General practice	1.79	4.26
02	General surgery	6.13	6.13
03	Allergy/Immunology	1.00	1.00
04	Otolaryngology	1.45	3.78
05	Anesthesiology	2.84	2.84
06	Cardiology	1.45	2.53
07	Dermatology	1.00	1.86
08	Family practice	1.79	4.26
10	Gastroenterology	2.05	3.49
11	Internal medicine	2.05	2.48
12	Osteopathic Manipulative Therapy	1.79	4.26
13	Neurology	2.52	2.74
14	Neurosurgery	12.00	12.00
16	Obstretics/Gynecology	2.15	5.63
18	Ophthalmology	1.24	2.31
20	Orthopedic surgery w/o Spinal	8.06	8.06
20	Orthopedic surgery with Spinal	8.89	8.89
22	Pathology	1.72	2.09
24	Plastic Surgery	6.92	6.92

Medicare Code	Medicare Description	Nonsurgical Risk Factor	Surgical Risk Factor
25	Physical Med & Rehab	1.26	1.26
26	Psychiatry	1.11	3.08
28	Colorectal surgery	4.08	4.08
29	Pulmonary disease	2.14	2.14
30	Diagnostic radiology	2.07	2.75
32	Anesthesiologist Assistant	2.84	2.84
33	Thoracic surgery	6.91	6.91
34	Urology	3.30	3.30
35	Chiropractic	1.26	1.26
36	Nuclear medicine	1.66	1.66
37	Pediatric medicine	1.76	2.42
38	Geriatric medicine	1.35	2.17
39	Nephrology	1.51	1.96
40	Hand surgery	4.71	4.71
41	Optometry	1.24	2.31
43	Certified Registered Nurse Assistant	3.04	3.71
44	Infectious disease	1.55	2.09
46	Endocrinology	2.03	2.09
47	Physiological Laboratory (independent)	3.04	3.71
48	Podiatry	3.04	3.71
50	Nurse Practitioner	3.04	3.71
62	Psychologist	1.11	3.08
65	Physical therapist (independent)	1.26	1.26
66	Rheumatology	2.11	2.11
67	Occupational therapist	1.11	1.11
68	Clinical Psychologist	1.11	3.08

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Medicare Code	Medicare Description	Nonsurgical Risk Factor	Surgical Risk Factor
69	Clinical Laboratory	3.04	3.71
70	Multi-Specialty Clinic or Group Practice	3.04	3.71
74	Radiation Therapy Center	2.43	2.43
76	Peripheral Vascular Disease	6.85	6.85
77	Vascular surgery	6.85	6.85
78	Cardiac surgery	7.18	7.18
79	Addiction Medicine	1.11	3.08
80	Licensed Clinical Social Worker	1.11	3.08
81	Critical Care (Intensivists)	3.04	3.71
82	Hematology	1.77	2.26
83	Hematology/oncology	2.05	2.11
84	Preventive medicine	1.26	1.26
85	Maxillofacial Surgery	6.92	6.92
86	Neuropsychiatry	1.11	3.08
89	Certified Clinical Nurse Specialist	3.04	3.71
90	Medical Oncology	2.05	2.48
91	Surgical Oncology	6.13	6.13
92	*Radiation oncology/therapy	2.43	2.43
93	Emergency medicine	3.79	4.55
94	Interventional Radiology	2.07	2.75
96	Optician	1.24	2.31
97	Physician Assistant	3.04	3.71
98	Gynecologist/oncologist	2.15	5.63

Note: If a specialty has only one risk classification, the same classification was used for both surgery and nonsurgery.

Note: For specialties with multiple risk classifications depending on the level of surgical involvement, the highest level of surgery was selected for surgery risk factor and the lowest level of surgery was selected for nonsurgery risk factor.

Note: CPT codes 59000-59899 were assigned the obstetrics risk factor (11.30) while all other OB/GYN procedures were assigned the gynecology surgical risk factor.

Comments and Responses

We received public comments on several malpractice issues. The comments and our responses are stated below.

Comment: Several comments were received that requested revisions to the data sources utilized in the development of resource-based malpractice RVUs. Specifically, commenters requested that we remove utilization for assistant-at-surgery claims from the calculation of resource-based malpractice RVUs because the utilization of assistant-at-surgery services artificially lowers the average risk associated with surgical services. Additionally, we also received comments that raised questions related to the ISO crosswalks and resulting risk factors that we used.

Response: We agree that assistants at surgery should not be reflected in the malpractice RVUs because they are not primarily responsible for performing the surgical procedures, and we are removing the assistant-at-surgery utilization, and associated risk factors, from the data that are used to calculate the resource-based malpractice RVUs. The inclusion of the lower assistant-at-surgery risk factors into the overall determination of some complex surgical services artificially lowers the average risk factor and resulting resource-based malpractice RVUs of these services.

Regarding the ISO Classifications and resulting risk factors that were applied to specialties, the majority of comments received did not offer substantive reasons or alternative methodologies for the proposed ISO crosswalks. We derived the ISO crosswalks, and resulting risk factors, based upon the review by both our contractor and CMS medical officers. Due to the lack of substantive alternatives in the comments received, we will retain the crosswalks that were proposed in the August 4, 2004 proposed rule (see Table 7) with the exception of orthopedic surgery and dermatology.

Comment: Several commenters believed that the August 2004 proposed rule that established risk factors of 7.46 for orthopedic surgery with spinal and 8.06 for orthopedic surgery without spinal were counterintuitive and needed revision.

Response: We agree with these comments and have revised the orthopedic surgery with spinal risk factor to reflect the risk factor identified in the rating manuals (8.89). In the proposed rule, the risk factors for orthopedic surgery with spinal and without spinal were taken from two separate sources (premium data and rating manuals, respectively) thus causing the anomalous result. See Table 7 for the revised orthopedic surgery risk factors.

Comment: Two commenters, including the American College of Dermatology believe that the use of the higher risk class of major surgery is inappropriate for dermatological services as the typical dermatological practice does not encompass major surgery but instead focuses on minor surgery in the office setting.

Response: We agree with these comments and will use the minor surgery and no-surgery risk classifications for dermatological services. See Table 7 for the revised dermatology risk factors. The impact of removing the assistant at surgery claims and revising the risk factor associated with orthopedic surgery with spinal is a 0.9 percent increase for neurosurgery and a 0.4 percent increase for orthopedic surgery over the malpractice RVUs shown in proposed rule. The effect of replacing the major surgery risk factor with the minor surgery risk factor for dermatology is a 0.9 percent decrease in total payments relative to the proposed rule.

Comment: One commenter states that the resource-based malpractice RVU methodology underestimates the cost of PLI for physicians who perform obstetric and gynecologic services. According to the commenter, eighty percent of OB/GYNs perform both obstetric and gynecologic services yet the risk factor for most services these physicians provide to Medicare beneficiaries is based on the much lower premiums paid by physicians who offer only gynecologic services.

Response: Although obstetricians and gynecologists' malpractice premiums can be appreciably different, most Medicare OB/GYN services are gynecological. Therefore, all Medicare OB/GYN procedures will be assigned a gynecology risk factor except in those instances where the service provided is clearly obstetrical in nature. CPT codes in the range of 59000–59899 are clearly obstetrical services and use the obstetrics risk factor (11.30).

Comment: One commenter felt that it was inappropriate to assign 0.00 malpractice RVUs to services that have physician work and have historically had a small amount of malpractice RVUs associated with them.

Response: We agree with this comment and will adjust these services in the final rule. All payable fee schedule services have some amount of PLI associated with their performance.

Comment: One commenter requested that we consider the implementation of the resource-based malpractice expense RVUs interim until the agency has worked with the medical community to ensure that the data and methodology utilized to calculate the malpractice RVUs are appropriate.

Response: We are continuing to work with the medical community to ensure that the methodology and data used to calculate the malpractice RVUs appropriately reflect the actual resource costs associated with professional liability insurance for physicians. Section 1848(c)(2)(B)(i) of the Act states that the Secretary is required to review the relative values not less often than every 5 years. If substantive information becomes available subsequent to the publication of the final malpractice RVUs, the statute allows us flexibility to review that information for possible inclusion in future malpractice RVU updates.

Comment: Several commenters requested that we use a methodology that would only account for the dominant specialty in the calculation of the service-specific resource-based malpractice RVUs. Commenters stated that a dominant specialty approach would be consistent with the ''typical'' service approach that we use throughout the resource-based physician payment system. Commenters also feel that a dominant specialty approach would more appropriately reflect the actual premium resource costs associated with the performance of individual services.

Response: We continue to believe that accounting for all specialties that perform a given service is the more appropriate and equitable methodology in establishing resource-based malpractice RVUs. Basing payment upon all specialties that perform a given service ensures that the actual professional liability insurance resource costs of all specialties are included in the calculation of the final malpractice RVUs. Using only the dominant specialty does not capture the true resource costs associated with a given service and under a relative value based system, results in the redistribution of RVUs based upon only partial data.

The dominant specialty approach is particularly vulnerable for calculating resource-based malpractice RVUs in services that are multi-disciplinary in nature. An example that illustrates the potentially distorting effect of the dominant specialty approach on multi-disciplinary services is the specialty utilization associated with a level III established office visit. Although over 35 different specialties perform a significant number of these services, a dominant specialty approach would base the malpractice RVUs on

approximately 2 specialties. High risk specialties such as neurosurgery, thoracic surgery, general surgery, and obstetrics and gynecology, which account for a small percentage of the total utilization but a large amount of total dollars, would no longer factor into the calculation of the malpractice RVU for this service. These four specialties alone account for nearly $300 million of the total dollars associated with a level III established office visit. The effect of removing these four high-cost, high-risk specialties from the calculation of the malpractice RVUs for this service would be an overall decrease in the malpractice RVUs, because the calculation would be based upon lower-cost, lower-risk specialties.

We disagree that a dominant specialty approach is consistent with the typical service approach used in the RUC survey process. Irrespective of the specialty performing a given service, we require that the typical service be the measurement tool for the calculation of final payments. The typical service approach utilized in the RUC survey process has never referred to the typical specialty performing a service, but instead to the typical type of service furnished. This typical service would encompass such things as the condition of the patient, the extent of the work, the staff needed to accomplish the service, and the respective resource inputs associated with the typical service.

We will continue to work with the RUC PLI Workgroup to identify alternatives to the dominant specialty approach. One alternative that we are currently exploring with the RUC PLI Workgroup is removing aberrant data from low utilization services.

Comment: One commenter suggested that we determine the exponential rate of growth in the PLI premium data from 2001 through 2003 to predict the 2004 premium data. This commenter believes that we should use only this predicted 2004 premium data in the calculation of resource-based malpractice RVUs.

Response: We disagree with the commenter's recommendation that predicted 2004 professional liability insurance premium data be utilized in the calculation of resource-based malpractice RVUs. The data sources that are currently used in the calculation of the 2005 resource-based malpractice RVUs consist of actual 2001 and 2002 premium data (when available) and projected 2003 premium data. Professional liability insurance has proven to be the most volatile data source that is used in the calculation of resource-based physician fee schedule RVUs. For this reason, we believe that it is inappropriate to use only one year of projected premium data.

Comment: Various specialty organizations request that we work with the RUC's Professional Liability Insurance (PLI) Workgroup to ensure that the medical community has input into the refinement of the malpractice RVUs.

Response: Over the course of the past year, we have been working with the RUC PLI Workgroup to solicit input on the methodology and data sources utilized to calculate resource-based malpractice RVUs. We continue to actively participate in the PLI Workgroup to keep both the workgroup and the various specialty organizations aware of our progress in the development and refinement of resource-based malpractice RVUs. We have forwarded all requested contractor reports, which outline both our methodology and data sources, to the RUC for review and comment. We agree with these comments and plan to continue our cooperative relationship with the RUC PLI Workgroup and various specialty organizations to ensure that the necessary specialty organizations are involved with both the premium collection efforts and the development and refinement of resource-based malpractice RVUs.

Comment: Tail coverage is designed to cover any claims that may be made against a new employee for services furnished on behalf of his or her old employer during the time that he or she is employed by the new employer. Several commenters suggested that we incorporate the cost of tail coverage in the determination of PLI annual premium data.

Response: Although we agree with the commenters that it might be desirable to use tail coverage premium data in addition to the annual premium data that are currently used in the revisions to resource-based malpractice RVUs, we have been unable to identify a nationally representative source of tail coverage premium data. We are continuing to work with the RUC PLI Workgroup, the AMA, and the various specialty organizations to identify a nationally representative source of tail coverage premium data for future rulemaking.

Comment: One commenter recommended that professional liability insurance data for all specialties should be used rather than the data from the top 20 Medicare specialties.

Response: Although it might be desirable to obtain premium data from every conceivable specialty in the practice of medicine, it is not possible to obtain this scope of data under the time constraints associated with collecting the most current premium data. In order to conduct surveys that collect the maximum amount of premium data from all geographic areas without being too intrusive to the State Departments of Insurance and private insurance companies, we chose to limit the scope of the data collection to the top 20 Medicare specialties. Further, utilizing PLI data from the top 20 Medicare specialties encompasses 80 percent of fee schedule services.

Comment: Several commenters requested that we use data from the Physician Insurers Association of America (PIAA) in the development of resource-based malpractice RVUs. This commenter further requested that we provide concise requirements for those data collection efforts.

Response: We did explore the use of data from PIAA in the development of resource-based malpractice RVUs. Unfortunately, the PIAA does not include actual physician claims-made premium data by insurer and specialty classification. The information that was available from PIAA ranged from insured demographics information to medical malpractice claims trends.

Regarding our criteria for premium data collection efforts, we have shared the criteria for those premium data collection efforts with the RUC PLI Workgroup.

Comment: Several commenters recommended that the malpractice RVUs should remain stable. Commenters suggested that any budget neutrality adjustments, positive or negative, that might occur due to the 5-year review of malpractice RVUs should be made to the conversion factor and not to the malpractice RVUs.

Response: We acknowledge the comments that suggest that any adjustments for budget neutrality not be performed on the RVUs, but we note that any budget neutrality adjustments to the RVUs do not change the relative relationship among the values for the services but instead uniformly change all relative values. Regarding malpractice RVUs specifically, malpractice RVUs are by nature not ''stable.'' When the malpractice RVUs are reviewed and updated, the malpractice RVUs associated with all services could potentially change. Additionally, for 2005, we are mandated by statute to apply at least a 1.5 percent increase to the conversion factor. Thus, if the budget neutrality associated with updated malpractice RVUs were negative, it would not be possible to ensure budget neutrality and comply with the statutory 1.5 percent update.

Comment: One commenter recommended that the exceptions to the surgical risk factor be modified to include coding changes since the initiation of the resource-based malpractice RVUs in 2000. The previous update to the malpractice RVUs made service-specific exceptions, whereby certain codes were assigned the higher surgical risk factor in the calculation of their final malpractice RVU. The commenter specifically requested that due to CPT coding modifications, the following codes should also receive this same coding modification and receive the greater of their actual average risk factor or the risk factor for cardiac catheterization: 92973–92974, 93501–93533, 93580–93581, 93600–93613, and 93650–93652.

Response: In order to retain the exceptions that were identified in the previous malpractice RVU update for this new series of services, we will assign the greater of the actual average risk factors or the risk factor for cardiac catheterization services.

Comment: Several commenters agreed with our use of the work RVUs as the best available data source for adjusting the malpractice RVUs for risk of service. These commenters noted, as we did, that the work RVUs are not a perfect proxy for risk of service, but are the best available source at this time. Commenters requested that we continue our use of work RVUs as the adjuster to malpractice RVUs for risk of service, but also requested that we be responsive to potential anomalies that may be identified.

Response: We agree with these comments and look forward to continuing our work with the various organizations to identify all potential anomalies in the malpractice RVUs.

Comment: One commenter expressed concern that, although malpractice premiums have increased for all specialty practices, some specialty practices will experience a decline in payments as a result of the 5-Year Review of malpractice RVUs. This commenter suggested that additional dollars need to be added to the system to account for rising PLI costs.

Response: The impact of the malpractice RVU revisions on an individual specialty organization is not a direct reflection of the increases or decreases in their malpractice premiums but instead reflects increases or decreases in a specific state's premiums as compared to the national average. In some instances, specialty organizations might have experienced slight increases in their respective malpractice premiums since the last malpractice RVU update, but these increases have occurred at a slower rate than the national average increase for all specialty organizations. The result is a negative impact on these specialties. Specialty organizations that have increased at a rate higher than the national average will experience positive impacts.

Comment: One commenter believes that additional dollars should be added to the Medicare physician fee schedule to account for escalating professional liability insurance premiums.

Response: The Medicare Economic Index (MEI) is the device by which additional dollars are added to the physician fee schedule. For 2005, the cost category associated with professional liability insurance has increased by 23.9 percent. However, for 2004 and 2005, section 601 of the MMA established an update of 1.5 percent.

Comment: The American College of Radiology (ACR) commented that there is an imbalance between the distribution of malpractice RVUs to the professional component and technical component of a service. The ACR requested that we work with ACR staff to identify alternative methodologies for the more appropriate valuation of technical component services.

Response: Physician work RVUs are used to adjust for risk of service. Because technical component services do not have physician work RVUs, they are still valued using charge-based RVUs instead of the resource-based malpractice RVU methodology. We look forward to working with the ACR and other interested specialty organizations to examine alternative methodologies that would allow technical component services to also reflect resource-based malpractice RVUs.

Final Decision

We are implementing the revised 2005 malpractice RVUs as proposed with the modifications noted in the discussions above. Additionally, we are continuing to work with the AMA's RUC to—

- Consider the appropriateness of a dominant specialty approach;
- Identify the most current nationally representative professional liability insurance premium data;
- Review the current ISO crosswalks; and
- Review aberrant data patterns in low-utilization services for possible inclusion in a future rulemaking cycle.

D. Coding Issues

1. Change in Global Period for CPT Code 77427, *Radiation Treatment Management, Five Treatments*

This code was included in the November 2, 1999 physician fee schedule final rule (64 FR 59380) and was effective for services beginning January 1, 2000. In that rule, and subsequent rules, we have applied a global indicator of ''xxx'' to this code, meaning that the global concept does not apply. It was brought to our attention that this global indicator is incorrect and that the code should be assigned a 90-day global period because the RUC valuation of this service reflected a global period of 90 days which we had accepted. Therefore, we proposed to correct the global indicator for this service to reflect a global period of 90 days (090).

Comment: Specialty organizations representing radiation oncology and radiology as well as individual physicians and providers, and the AMA, all expressed concern about this proposal to change the global period for CPT code 77427. The commenters stated that this code is universally recognized as a recurring service that can be provided multiple times during a course of radiation. This code is usually submitted once for each group of five treatments (or fractions) and represents substantial services furnished during that group (typically 1 week) of five treatments. Commenters believe this proposed change would—

- Contradict the current CPT definitions;
- Not reflect the process of care for radiation;
- Countervene the essence of the RUC valuations; and
- Negate the guidelines that we previously issued.

Because a change in the global period could have a significant impact on the process of care for radiation oncology, commenters urged us to withdraw this proposal or to delay implementation until there is further discussion with the specialty organizations and the RUC, and clarification of billing matters related to this proposed change are provided.

Response: Based on the concerns raised by the commenters, we are not changing the global period for this service as proposed.

Result of Evaluation of Comments

We are retaining the global period of ''xxx'' for CPT code 77427.

2. Requests for Adding Services to the List of Medicare Telehealth Services

As discussed in the proposed rule (69 FR 47510), section 1834(m) of the Act defines telehealth services as professional consultations, office and other outpatient visits, and office psychiatry services defined as of July 1, 2000 by CPT codes 99241 through 99275, 99201 through 99215, 90804 through 90809, and 90862. In addition, the statute requires us to establish a process for adding services to, or deleting services from, the list of telehealth services on an annual basis. In the CY 2003 final rule, we established a process for adding to or deleting services from the list of Medicare telehealth services (67 FR 79988). This process provides the public an opportunity on an ongoing basis to submit requests for adding a service. We assign any request to add a service to the list of Medicare telehealth services to one of the following categories:

• *Category 1:* Services that are similar to office and other outpatient visits, consultation, and office psychiatry services. In reviewing these requests, we look for similarities between the proposed and existing telehealth services in terms of the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service, for example, the use of interactive audio and video equipment.

• *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the use of a telecommunications system to deliver the service produces similar diagnostic findings or therapeutic interventions as compared with the face-to-face ''hands on'' delivery of the same service. Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to a face-to-face delivery of the requested service.

Requests for adding services to the list of Medicare telehealth services must be submitted and received no later than December 31st of each calendar year to be considered for the next proposed rule. For example, requests submitted in CY 2003 are considered for the CY 2005 proposed rule. For more information on submitting a request for addition to the list of Medicare telehealth services, visit our Web site at *http://www.cms.hhs.gov/physicians/telehealth*.

We received the following public requests for addition in CY 2003:

• Inpatient hospital care (as represented by CPT codes 99221 through 99223 and 99231 through 99233).

• Emergency department visits (as defined by CPT codes 99281 through 99285).

• Hospital observation services (as represented by CPT codes 99217, 99218 through 99220).

• Inpatient psychotherapy (as defined by CPT codes 90816 through 90822).

• Monthly management of patients with end-stage renal disease (ESRD), (as represented by HCPCS codes G0308 through G0319).

• Speech and audiologist services (as defined by CPT code range 92541 through 92596).

• Case management (as identified by CPT codes 99361 and 99362)

• Care plan oversight services (as represented by CPT codes 99374 and 99375).

After reviewing the public requests for addition, we proposed to add ESRD–related services as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317, and G0318 to the list of Medicare telehealth services. However, we specified that the required clinical examination of the vascular access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, certified nurse specialist (CNS), nurse practitioner (NP), or physician's assistant (PA). An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit Monthly Capitation Payment (MCP) code and the 4 or more visit MCP code.

Moreover, we proposed to add the term ''ESRD–related visits'' to the definition of Medicare telehealth services at § 410.78 and § 414.65 as appropriate.

We did not propose to add any additional services to the list of Medicare telehealth services for CY 2005.

For further information on the addition to the list of telehealth services, see the **Federal Register** dated August 5, 2004 (69 FR 47510).

Inpatient Hospital Care, Hospital Observation Services, Inpatient Psychotherapy, and Emergency Department Services

Comment: We received conflicting comments on our proposal not to add inpatient hospital care, hospital observation services, inpatient psychotherapy, and emergency department services to the list of approved telehealth services. For example, one professional society supported our proposal not to add inpatient hospital care, hospital observation services, inpatient psychotherapy, and emergency department services to the list. That commenter believes conclusive efficacy data is necessary before adding the aforementioned services. Likewise, an association representing emergency department management agreed that emergency department visits should not be added to the list of Medicare telehealth services. That commenter believes that hospitals in rural areas have physicians with sufficient experience to handle the complexities of emergent care.

An association representing family physicians agreed with our proposal not to add inpatient hospital care and hospital observation services. However, they disagreed with our proposal not to add emergency department visits to the list of Medicare telehealth services. The commenter stated that emergency department visits should not be assigned to category 2 based on the acuity of the patient. The commenter believes that the range of potential acuity is the same in the emergency room as it is in the office setting and noted that office and other outpatient visits are currently on the list of Medicare telehealth services. A professional society encouraged us to reexamine the request to add inpatient hospital care, observation services, and inpatient psychotherapy to the list of Medicare telehealth services in the future.

Response: We agree that the acuity for some patients may be the same in the emergency department as in a physician's office. However, we also believe that more acutely ill patients are more likely to be seen in the emergency department. Although telehealth is an acceptable alternative to face-to-face ''hands on'' patient care in certain settings, the potential for misdiagnosis and/or mismanagement, with more serious consequences, exists in high acuity environments like the emergency department when telehealth is used as a replacement for an onsite physician or practitioner. The practice of emergency medicine often requires frequent patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants. We do not have evidence suggesting the use of telehealth could be a reasonable surrogate service for this type of care. In the absence of sufficient evidence that illustrates that the use of a telecommunications system produces

similar diagnoses or therapeutic interventions as would the face-to-face delivery of inpatient hospital care, emergency department visits, hospital observation services, and inpatient psychotherapy, we do not plan to add these services to the list of approved telehealth services. As discussed in the proposed rule, we believe that the current list of Medicare telehealth services is appropriate for hospital inpatients, emergency room cases, and patients designated as observation status. If guidance or advice is needed in these settings, a consultation may be requested from an appropriate source.

Comment: A telehealth association and a telehealth network requested that we clarify what consultation codes could be used for hospital inpatients, emergency room cases, and patients designated as observation status.

Response: The appropriate consultation code depends on the admission status of the beneficiary. When the beneficiary is an inpatient of a hospital, the physician or practitioner at the distant site bills an initial or follow-up inpatient consultation as described by CPT codes 99251 through 99263. For the hospital observation setting and emergency department, the appropriate office or other outpatient consultation code is CPT codes 99241 through 99245.

Comment: Some commenters believe that hospital inpatient care, inpatient psychotherapy, observation services, and emergency department visits should all be assigned to category 1 because they are clinically the same as a consultation. Moreover, the commenters expressed their opinion that a telecommunications system would not substitute for an in-person practitioner for the requested hospital services.

Response: We agree that the key components of a consultation are similar to inpatient hospital care, observation services, and emergency department visits. However, a consultation service is distinguished from the requested hospital services because it is provided by a physician or practitioner whose opinion or advice regarding evaluation and management of a specific problem is requested by another physician or appropriate source. The ongoing management of the patient's condition remains the responsibility of the practitioner who requested the consultation. As discussed in our response to another comment, a consultation may be provided as a Medicare telehealth service for hospital inpatients, emergency room cases, and patients designated in observation status.

In furnishing a consultation as a telehealth service, the physician at the distant site provides additional expertise, to ensure optimal patient outcomes. For consultation services, a practitioner is available to manage the patient at the originating site. However, adding the requested hospital services would permit a telecommunications system to be used as a substitute for an onsite practitioner because the physician or practitioner at the distant site assumes responsibility for the ongoing management of the patient's condition.

End Stage Renal Disease—Monthly Management of Patients on Dialysis

Comment: Many commenters, including a telehealth association, a nephrology nurses association, a renal physicians association, a health system, a community hospital, a telemedicine law group, and others applauded our proposal to add the ESRD-related services with 2 or 3 visits per month and ESRD-related services with 4 or more visits per month to the list of Medicare telehealth services. For example, two commenters believe that adding these services will help provide dialysis patients living in rural areas sufficient access to nephrology specialists and will save both patients and practitioners a significant amount of travel time. Additionally, many commenters expressed strong support for not permitting the visit that includes a clinical examination of the vascular access site to be added to the list of Medicare telehealth services and agreed that this exam should be furnished in person.

Response: We agree with the comments.

Comment: With regard to furnishing ESRD-related visits under the MCP, a nephrology association suggested that we permit the use of e-mail and telephone conferencing for one year. The commenter believes this grace period would enable physicians and originating sites to acquire the necessary technology and execute their implementation plans. Additionally, an association of kidney patients questioned whether telehealth services would be available to ESRD patients in non-rural areas.

Response: Services added to the list of Medicare telehealth services are subject to the requirements and conditions of payment in the law and regulations. Under the Medicare telehealth provision, the use of an interactive audio and video telecommunications system that permits real-time interaction between the patient, physician or practitioner at the distant site, and telepresenter (if necessary) is a substitution for the face-to-face requirements under Medicare. Electronic mail systems and telephone calls are specifically excluded from the definition of an interactive telecommunications system. Moreover, we do not have the legislative authority to expand the geographic areas where telehealth services may be furnished. Telehealth services may only be furnished in non-Metropolitan Statistical Area counties or rural health professional shortage areas.

Comment: An association representing kidney patients questioned whether we plan to evaluate the provision of telehealth services to ESRD patients to determine best practices.

Response: We believe that most physicians and practitioners will use telehealth services for providing additional visits required under the MCP as appropriate to manage their patients on dialysis. However, we would welcome specific data on best practice methods for furnishing ESRD-related services as telehealth services.

Comment: Some commenters indicated a belief that the ESRD-related services were assigned to category 2 for review. For example, one telehealth group believed that a discrepancy exists between the rationale we used to add ESRD-related services to the list of telehealth services and our decision not to add inpatient hospital care, observation services, inpatient psychotherapy, and emergency department visits. The commenter stated that ESRD-related services were added in the absence of randomized clinical trials or comparison studies and mentioned that the same level of evidence was submitted for ESRD-related services as for other requests (for example, inpatient hospital services). The commenter requested clarification on the method used to assign services to category 1 or category 2.

Response: As discussed in the proposed rule, the MCP represents a range of services provided during the month, including various physician and practitioner services, such as the establishment of a dialyzing cycle, outpatient evaluation and management of the dialysis visit(s), telephone calls, and patient management as well as clinically appropriate physician or practitioner visit(s) during the month. At least one of the visits must include a clinical examination of the vascular access site furnished face-to-face, ''hands-on'' by a physician, CNS, NP, or PA.

We considered the outpatient evaluation and management of the dialysis visits to be similar to an office

visit and other outpatient visits currently on the list of Medicare telehealth services. However, we believe that the clinical examination of the vascular access site is not similar to the existing telehealth services, and, therefore, it meets the criteria for a category 2 request. We did not propose to add a comprehensive visit including a clinical examination of the vascular access site, to the list of Medicare telehealth services because the requestor did not provide comparative analyses illustrating that the use of a telecommunications system is an adequate substitute for a face-to-face clinical examination of the vascular access site. However, as discussed in the proposed rule, we do believe that the subsequent visits to monitor the patient's condition met our criteria for approving a category 1 request. For category 1 services, we look for similarities between the proposed and existing telehealth services in terms of the roles of, and interactions among, the beneficiary, the physician or practitioner at the distant site, and, if necessary, the telepresenter.

Therefore, we proposed that the MCP physician, that is, the physician or practitioner responsible for the evaluation and management of the patient's ESRD, and other practitioners within the same group practice or employed by the same employer or entity, may furnish additional ESRD-related visits as telehealth services using an interactive audio and video telecommunications system. However, for purposes of billing the MCP, at least one visit must include a clinical examination of the vascular access site, and must be furnished face-to-face, ''hands on'' by a physician, CNS, NP, or PA each month.

Comment: One commenter requested that we allow a physician or surgeon located at the originating site (who is not the MCP physician) to furnish ESRD-related visits involving the clinical examination of the vascular access site. The commenter stated that having a physician or surgeon skilled in vascular access management available to work in coordination with the MCP physician is necessary for geographically remote areas such as Alaska and in severe weather conditions. The commenter believes that this type of arrangement is well suited for telehealth.

Response: The MCP physician may use another physician to provide some of the visits during the month however, the non-MCP physician must have a relationship with the billing physician such as a partner, employees of the same group practice or an employee of the MCP physician, for example, the physician at the originating site is either a W–2 employee or 1099 independent contractor.

Case Management and Care Plan Oversight (Team Conferences and Physician Supervision)

A telehealth association and a network of clinics requested clarification on—

- The scope of authority relating to the addition of services that do not require a face-to-face encounter with the patient; and
- Whether our policy for care plan oversight is similar to the interpretation of an x-ray and other services that do not require a face-to-face encounter.

Additionally, a neurological society urged us to reconsider our decision not to add medical team conferences to the list of telehealth services. The commenter argued that adding medical team conferences as a telehealth service would improve the quality of the care plan and save time for all physicians involved in the patient's care.

Response: We add services to the list of Medicare telehealth services that traditionally require a face-to-face physician or practitioner encounter. The use of an interactive audio and video telecommunications system, permitting real time interaction between the beneficiary, physician or practitioner at the distant site, and telepresenter (if necessary) is a substitute for face-to-face requirements under Medicare. Services not requiring a face-to-face encounter with the patient that may be furnished through the use of a telecommunications system are already covered under Medicare. As discussed in chapter 15, section 30 of the Medicare Benefit Policy Manual, payment may be made for physicians' services delivered via a telecommunications system for services that do not require a face-to-face patient encounter. The interpretation of an x-ray, electrocardiogram, electroencephalogram and tissue samples are listed as examples of these services. The Medicare Benefit Policy Manual may be found on our Web site at *http://www.cms.hhs.gov/manuals/* by selecting the internet-only manuals link.

Medical team conferences and monthly physician supervision do not require a face-to-face encounter with the patient, and, thus, a telecommunications system may be used to accomplish them. However, Medicare payment for CPT codes 99361, 99362, and 99374 are bundled; no separate payment is made under the Medicare program for these services, and CPT code 99375 (physician supervision; 30 minutes or more) is invalid for Medicare payment purposes. We pay for monthly physician supervision as described by HCPCS codes G0181 and G0182.

Process for Adding Services to the List of Medicare Telehealth Services

Comment: We received conflicting comments on our process for adding services to the list of Medicare telehealth services. For example, a surgeons' association supported the evidence-based approach for adding category 2 services. However, a school of medicine and a telemedicine and electronic health group believe that we should consider changing our categorical system for adding a service to the list of Medicare telehealth services, specifically, in relation to the requested hospital services for hospital inpatients, emergency room cases, and patients designated as observation status.

One of the commenters believes that the decision to use a telehealth system should be up to the physician or practitioner at the distant site. The commenter argues that, if the physician or practitioner at the distant site is not comfortable in making a clinical judgment, the patient may be asked to travel to the physician's office for further examination.

Moreover, the commenter contends that the nature of telehealth services is not well suited for clinical trials and that the evidence that we require under category 2 may never be obtained because of the lack of reimbursement. As an alternative, the commenters recommended a method of review that considers—

- Clinical utilization of the requested telehealth service;
- The opinions of physicians and practitioners furnishing the telehealth service; and
- The opportunity for the physicians and practitioners to prove the service is being delivered appropriately via telecommunications system.

Response: We believe that the current method for reviewing requests for addition already considers the criteria mentioned by the commenter. The process for adding services to the list of Medicare telehealth services provides the public an ongoing opportunity to propose services that they believe are appropriate for Medicare payment. Requestors may submit data showing that patients who receive the requested service via telecommunications system are satisfied with the service delivered and that the use of a telecommunications system does not change the diagnosis or therapeutic

interventions for the requested service. Additionally, we believe that having different categories of review allows us to add requested services that are most like the current telehealth services (for example, office visits, consultation, and office psychiatry) without subjecting these requests to a comparative analysis.

Since establishing the process to add services to the list of Medicare telehealth services, we have added the psychiatric diagnostic interview examination and have proposed specific ESRD-related services for the CY 2005 rule.

Comment: One commenter recommended that we replace the term face-to-face with ''in-person''. The commenter believes that the term ''in-person'' is a better description of an encounter where the practitioner is in the same physical location as the beneficiary.

Response: The commenter's suggestion to use the term ''in-person'' to describe an encounter where the physician or practitioner and the beneficiary are physically in the same room has been noted. We will consider the commenter's suggestion as we discuss Medicare telehealth payment policy in the future.

Report to Congress

Comment: An audiology society and a language and hearing association strongly believe that most audiology services and speech therapy can be furnished remotely as telehealth services. To that end, many commenting groups and associations requested that we complete the report to Congress (as required by section 223(d) of the BIPA) and urged us to recommend adding speech language pathologists and audiologists as medical professionals that may provide and receive payment for Medicare telehealth services.

Moreover, in light of the proposed addition of ESRD-related services to the list of telehealth services, many of these same commenters along with a nephrology society requested that we recommend adding dialysis facilities to the list of originating sites. One commenter requested that we add the patient's home to the definition of an originating site.

Response: The report to Congress on additional sites and settings, practitioners, and geographic areas that may be appropriate for Medicare telehealth payment is under development. We are considering the suggestions raised by the commenters as we formulate our recommendations to the Congress.

Result of Evaluation of Comments

We are adding ESRD-related services as described by G0308, G0309, G0311, G0312, G0314, G0315, G0317, and G0318 to the list of Medicare telehealth services. However, we will require that the complete assessment must include a face-to-face clinical examination of the vascular access site furnished ''hands on'' (without the use of an interactive telecommunications system) by a physician, clinical nurse specialist, nurse practitioner, or physician's assistant. An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit MCP code and the 4 or more visit MCP code. Additionally, we are adding the term ''ESRD–related visits'' to the definition of Medicare telehealth services at § 410.78 and § 414.65, as appropriate.

3. National Pricing of G0238 and G0239 Respiratory Therapy Service Codes.

In the 2001 final rule, we created the following three G codes for respiratory therapy services:

- G0237 Therapeutic procedures to increase strength or endurance of respiratory muscles, face-to-face, one-on-one, each 15 minutes (includes monitoring).
- G0238 Therapeutic procedures to improve respiratory function, other than ones described by G0237, one-on-one, face-to-face, per 15 minutes (includes monitoring).
- G0239 Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).

We assigned RVUs to one of the codes (G0237), and indicated that the other two codes (G0238 and G0239) would be carrier-priced. Since the services represented by these codes are frequently being performed in comprehensive outpatient rehabilitation facilities (CORFs), paid under the physician fee schedule through fiscal intermediaries, there has been some uncertainty surrounding the payment for the carrier-priced services. We believe assigning RVUs to G0238 and G0239 will provide needed clarity. Since these services are typically performed by respiratory therapists, we did not assign physician work to G0237, and we did not propose work RVUs for either G0238 or G0239.

Therefore, we proposed to value nationally the practice expense for these services using the nonphysician work pool. We proposed to crosswalk practice expense RVUs for G0238 to those for G0237 based on our belief that the practice expense for the activities involved is substantially the same for both services.

For G0239, we believe a typical group session to be 30 minutes in length and to consist of 3 patients. Therefore, for the practice expense RVUs for G0239, we proposed using the practice expense RVUs of G0237 reduced by one-third to account for the fact that the service is being provided to more than one patient simultaneously and each patient in a group can be billed for the services of G0329.

We also proposed a malpractice RVU of 0.02, the malpractice RVU assigned to G0237, for these two G–codes.

Comment: Commenters supported the national pricing for these 2 G–codes, G0238 and G0239. However, these organizations disagree with our RVU assignment. Specifically, most commenters disagreed with the lack of physician work RVUs and also believed that the malpractice RVU is inadequate to reflect the costs associated with the delivery of the services. These organizations contend that pulmonary rehabilitation services ''include a physician-directed individualized plan of care using multidisciplinary qualified health professionals to enhance the effective management of pulmonary diseases and resultant functional deficits.'' They believe that beneficiaries may receive pulmonary rehabilitation services at physician offices, outpatient departments of acute care hospitals, CORFs and rehabilitation clinics. The commenters noted that physicians and qualified nurse practitioners (NPs) and PAs order, supervise, and approve the plans of care for patients receiving respiratory therapy services, irrespective of the delivery setting.

Because respiratory rehabilitation is often furnished in a physician office, these organizations believe the malpractice RVU assigned is inadequate to account for the physician involvement and requested that a more appropriate risk factor be used.

Response: Because we believe that respiratory therapists (RTs) typically deliver these services, it would be inappropriate to assign a physician work RVU to these services. The malpractice RVU of 0.02 is similar to RVUs of therapeutic procedures delivered by physical and occupational therapists for similar services, including procedures performed one-on-one and in groups. We believe that the 0.02 malpractice RVU fairly represents the risk value inherent in the provision of these procedures. However, because the commenters expressed concerns about work and malpractice RVUs, we are assigning these RVUs on an interim

basis, and we are requesting that the RUC or HCPAC consider this series of three G–codes at an upcoming meeting.

Because RTs cannot directly bill Medicare for their services, these G-codes can only be billed as incident to services in physician offices and outpatient hospital departments or as CORF services. When performed in the CORF setting, these services must be delivered by qualified personnel, that is, RTs and respiratory therapy technicians, as defined at § 485.70. The CORF benefit requires the physician to establish the respiratory therapy plan of care and mandates a 60-day recertification for therapy plans of care, including physical therapy (PT), occupational therapy (OT), speech language pathology (SLP), and respiratory therapy. As we stated in the December 31, 2002 final rule, we believe that specially trained professionals (that is, registered nurses, physical therapists and occupational therapists) can also provide these services.

These respiratory therapy G-codes were designed to provide more specific information about the medically necessary services being provided to improve respiratory function and to substitute for the physical medicine series of CPT codes 97000 through 97799, except when services are furnished and meet all the requirements for physical and occupational therapy services.

Comment: While three commenters voiced concerns about the significant undervaluing of these codes, one commenter noted that the practice expense RVUs fail to recognize the intensity of services and the cost of monitoring and other equipment associated with providing these services.

Response: We agree that the practice expenses, particularly the equipment, for G0237 and G0238 are not equivalent and that there are more resources required to provide the medically necessary services of G0238. The necessary monitoring equipment referenced by commenters were considered at the time G0327 was originally valued. The appropriate direct inputs will be added to the practice expense database. However, we identified the omission of therapeutic exercise equipment for G0238 and G0239 and we will also add this to the practice expense database.

Result of Evaluation of Comments

We are assigning practice expense and malpractice RVUs to G0238 and G0239 and will add the additional items to the practice expense database. These codes are being valued in the nonphysician work pool as proposed. We will also ask the RUC or HCPAC to consider these codes.

4. Bone Marrow Aspiration and Biopsy through the Same Incision on the Same Date of Service.

In the August 5, 2004 rule, we proposed a new add-on G-code, G0364 (proposed as G0XX1): Bone marrow aspiration performed with bone marrow biopsy through same incision on same date of service. The physician would use the CPT code for bone marrow biopsy (38221) and G0364 for the second procedure (bone marrow aspiration).

We believe that there is minimal incremental work associated with performing the second procedure through the same incision during a single encounter. We estimated that the time associated with this G-code is approximately 5 minutes based on a comparison to CPT code 38220 bone marrow aspiration which has 34 minutes of intraservice time and a work RVU of 1.08 work when performed on its own. We proposed 0.16 work RVUs for this new add-on G-code and malpractice RVUs of 0.04 (current malpractice RVUs assigned to CPT code 38220). For practice expense, we proposed the following practice expense inputs:

— Clinical staff time: Registered nurse—5 minutes Lab technician—2 minutes
— Equipment: Exam table

We also proposed a ZZZ global period (code related to another service and is always in the global period of the other service) for this add-on code since this code is related to another service and is included in the global period of the other service.

In the August 5, 2004 proposed rule, we also stated that if the two procedures, aspiration and biopsy, are performed at different sites (for example, contralateral iliac crests, sternum/iliac crest or two separate incisions on the same iliac crest), the −59 modifier, which denotes a distinct procedural service, is appropriate to use and Medicare's multiple procedure rule will apply. In this instance, the CPT codes for aspiration and biopsy are each being used.

Comment: Many commenters supported creation of this G-code; however, all commenters stated that the time for this procedure (5 minutes) was substantially underestimated. Commenters recommended increasing the added incremental time associated with the aspiration to 15 minutes. One commenter noted that this time is needed for the actual aspiration procedure, approving the quality of the aspiration, collecting flow cytometry and chromosome studies, preparing additional slides, ordering appropriate lab tests on the slides, and performing the added recordkeeping and documentation. Another commenter provided a detailed description of the activities involved in this procedure. Commenters also recommended that the practice expense input for the nurse assisting with the procedure should be increased to 15 minutes.

Response: We continue to believe that the proposed 5 minutes of physician time, 5 minutes of registered nurse time, and 2 minutes of lab technician time reflect the additional effort involved when a bone marrow aspiration is performed in conjunction with a bone marrow biopsy through the same incision during a single encounter. It is our understanding that some of the activities attributed to the additional 15 minutes of physician work generally are performed by ancillary staff, for example, preparing slides. While we appreciate the information provided, we believe that the majority of the effort and specific tasks discussed are accounted for in the CPT code for bone marrow biopsy (38221) which is the primary code being billed.

Comment: Two physician specialty societies, representing radiologists and interventional radiologists, questioned the need for the proposed code, because the multiple surgical discount rule that reduces payment for a subsequent lower valued service applies, thereby taking into account any savings in physician work. If we choose to proceed with the proposal, the commenter recommended the RVUs be consistent with those determined using the current values for CPT codes 38220 and 38221 and the multiple surgical discount rule.

Response: One of the primary reasons for our proposal for this G-code was that we believe that, even with the application of the multiple procedure reduction, we would be overpaying for these services when they are performed on the same day, at the same encounter and using the same incision.

Result Of Evaluation of Comments

We are finalizing our proposal and using new G-code G0364, Bone marrow aspiration performed with bone marrow biopsy through the same incision on the same date of service. Payment is based on the work and malpractice RVUs and practice expense inputs proposed and the global period for this service is ''ZZZ''.

5. Q-Code for the Set-Up of Portable X-Ray Equipment

The Q-code for the set-up of portable x-ray equipment, Q0092, is currently paid under the physician fee schedule and is assigned an RVU of 0.33. In 2004, this produces a national payment of $12.32. This set-up code encompasses only a portion of the resources required to provide a portable x-ray service to patients. In 2003, portable x-ray suppliers received total Medicare payments of approximately $208 million. More than half of these payments (approximately $116 million) were for portable x-ray transportation (codes R0070 and R0075). The portable x-ray set-up code (Q0092) generated approximately $19 million in payments. The remainder of the Medicare payments for portable x-ray services (approximately $73 million) were for the actual x-ray services themselves.

As discussed in the August 5, 2004 proposed rule, the Conference Report accompanying the Consolidated Appropriations Bill, H.R. 2673, (Pub. L. 108–199, enacted January 23, 2004) urged the Secretary to review payment for this code, and the portable x-ray industry has also requested that we reexamine payments for this code.

Q0092 is currently priced in the nonphysician work pool. At the time we modeled this change for the proposed rule, removing this code from the nonphysician work pool had an overall negative impact on payments to portable x-ray suppliers (as a result of decreases to radiology codes that remain in the nonphysician work pool) and a negative impact on many of the codes remaining in the nonphysician work pool. An alternative to national pricing of portable x-ray set-up would be to require Medicare carriers to develop local pricing as they do currently for portable x-ray transportation. We requested comments on whether we should pursue national pricing for portable x-ray set-up outside of the nonphysician work pool or local carrier pricing for 2005, or whether we should continue to price the service in the nonphysician work pool.

Comment: Most commenters recommended removing portable x-ray from the nonphysician work pool, using the ''existing data'' from the American College of Radiology (ACR) supplemental practice expense survey as the practice expense per hour proxy. However, the National Association of Portable X-Ray Suppliers (NAPXP) requested additional time to review information they received from us just 3 days before the close of the comment period. This association requested that they be allowed to submit supplemental comments.

Response: ACR requested that we delay incorporating their survey data for 1 year. Using the data for one code, as proposed by commenters, would be inconsistent with that request. We believe it is inappropriate to use the new survey data for this code but no other code. Even if we removed the set-up code from the nonphysician work pool and calculated its practice expense RVU using the ACR data, the increase in payment for the portable x-ray set-up code would be largely offset by lower payment for x-ray services. Payments for other services in the nonphysician work pool would also decline affecting other specialties, such as radiology, radiation oncology, cardiology, allergy, audiology and others. Further, the portable x-ray set-up code is yet to be refined, and we believe that the 45 minutes of staff time that is used to determine its value is likely overstated. We believe it is preferable to address refinement of the code and pricing the service outside of the nonphysician work pool together. Therefore, in 2005, we are continuing to price this service within the nonphysician work pool.

The NAPXP requested more time to review the data we supplied them. NAPXP's comment implying that we withheld ''data'' from them is simply wrong. In an effort to explain the theoretical reasons for our statements that removing this service from the nonphysician work pool could lower overall payments to portable x-ray suppliers, we prepared an illustration for another association as a follow-up request after a meeting, where we were asked to explain our proposed rule analysis. The explanation contained no new data. Moreover, we provided the explanatory information to NAPXP as soon as they requested it. Since the information NAPXP complains about was illustrative only, we do not believe NAPXP has been prejudiced in any way. Moreover, we are willing to explain the information to NAPXP and to consider any comments they may have as we consider changes to the practice expense methodology for 2006.

6. Venous Mapping for Hemodialysis

In the August 5, 2004 rule, we proposed a new G-code (G0XX3: Venous mapping for hemodialysis access placement (Service to be performed by operating surgeon for preoperative venous mapping prior to creation of a hemodialysis access conduit using an autogenous graft). Autogenous grafts have longer patency rates, a lower incidence of infection and greater durability than prosthetic grafts. Use of autogenous grafts can also result in a decrease in hospitalizations and morbidity related to vascular access complications. We stated that creation of this G-code will enable us to distinguish between CPT code 93971 (Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study) and G0XX3 in order to allow us to track use of venous mapping for quality improvement purposes.

We also proposed that this G-code be billed only by the operating surgeon in conjunction with CPT codes 36819, 36821, 36825, and 36832 and that we would not permit payment for CPT code 93971 when this G-code is billed, unless code CPT 93971 was being performed for a separately identifiable clinical indication in a different anatomic region.

We proposed to crosswalk the RVUs for the new G-code from those of CPT code 93971 and also assigned this new G-code a global period of ''XXX,'' which means that the global concept does not apply.

Comment: Commenters representing specialty societies and individual providers were generally supportive of the proposal for this new code, but expressed the following three primary concerns:

- Commenters did not agree with restricting this code to the operating surgeon, stating that such a restriction could limit access and serve as a barrier in providing this service. They also stated that this proposed restriction is not reflective of current practice, since nonsurgeons often perform this procedure.
- Commenters did not agree with the proposed descriptor. They indicated that the proposed descriptor did not reflect the procedure as it is now performed and suggested (a) alternate wording, such as ''vascular mapping,'' ''autogenous AV fistula,'' and ''prosthetic graft,'' ''vessel mapping;'' (b) that two G-codes should be created to distinguish between a complete bilateral and unilateral or limited studies. Other commenters noted that the proposal did not distinguish between mapping by venography or ultrasound (duplex), and some commenters suggested creating an additional G-code to distinguish between these procedures.
- Commenters stated that the comparison to CPT code 93971 in the proposed rule undervalues the service. While there are differences, the closer analogue in terms of time and resources required is CPT code 93990, Duplex scans of hemodialysis access.

Response: We proposed the G-code to create the opportunity for us to analyze

the relationship between venous mapping utilization and fistula formation.

Based on the comments we received, we are revising the code descriptor to enable clinicians, other than the operating surgeon, who provide care to ESRD patients the opportunity to bill for this service.

We believe that vessel mapping requires the assessment of the arterial and venous vessels in order to provide the information necessary for the creation of an autogenous conduit. Therefore, we are also revising payment for this code and will crosswalk it to CPT code 93990 for work, malpractice, and practice expense RVUs because these RVUs more appropriately reflect the work and resources of this new G-code. The G-code and descriptor for this service will be G0365, Vessel mapping of vessels for hemodialysis access (Services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow). This code can only be used in patients who have not had a prior hemodialysis access prosthetic graft or autogenous fistula and is limited to two times per year.

We will not permit separate payment for CPT code 93971 when this G-code is billed, unless CPT code 93971 is being performed for a separately identifiable indication in a different anatomic region. We also note that other imaging studies may not be billed for the same site on the same date of service unless an appropriate ''KO'' modifier indicating the reason or need for the second imaging study is provided on the claim form.

We will follow the utilization closely this year to better understand whether this code is used as intended.

III. Provisions Related to the Medicare Modernization Act of 2003

A. Section 611—Preventive Physical Examination

Section 611 of the MMA provides for coverage under Part B of an initial preventive physical examination (IPPE) for new beneficiaries, effective for services furnished on or after January 1, 2005, subject to certain eligibility and other limitations.

In the August 5, 2004 proposed rule, we described a new § 410.16 (Initial preventive physical examination: conditions for and limitations on coverage) that would provide for coverage of the various IPPE services specified in the statute. As provided in the statute, this new coverage allows payment for one IPPE within the first 6 months after the effective date of the beneficiary's first Part B coverage period, but only if that coverage period begins on or after January 1, 2005. To implement the statutory provisions, we proposed definitions of the following terms:

- Eligible beneficiary;
- An initial preventive physical examination;
- Medical history;
- Physician;
- Qualified NPP;
- Social History, and
- Review of the individual's functional ability and level of safety.

In keeping with the language of section 611 of the MMA, we defined the term ''eligible beneficiary'' to mean individuals who receive their IPPEs within 6 months after the date of their first Medicare Part B coverage period, but only if their first Part B coverage period begins on or after January 1, 2005. This section also defines the term ''Initial Preventive Physical Examination'' to mean services provided by a physician or a qualified NPP consisting of: (1) A physical examination (including measurement of height, weight, blood pressure, and an electrocardiogram, but excluding clinical laboratory tests) with the goal of health promotion and disease detection; and (2) education, counseling, and referral for screening and other covered preventive benefits separately authorized under Medicare Part B.

Specifically, section 611(b) of the MMA provides that the education, counseling, and referral of the individual by the physician or other qualified NPP are for the following statutory screening and other preventive services authorized under Medicare Part B:

- Pneumococcal, influenza, and hepatitis B vaccine and their administration;
- Screening mammography;
- Screening pap smear and screening pelvic exam services;
- Prostate cancer screening services;
- Colorectal cancer screening tests;
- Diabetes outpatient self-management training services;
- Bone mass measurements;
- Screening for glaucoma;
- Medical nutrition therapy services for individuals with diabetes or renal disease;
- Cardiovascular screening blood tests; and
- Diabetes screening tests.

Based on the language of the statute, our review of the medical literature, current clinical practice guidelines, and United States Preventive Services Task Force (USPSTF) recommendations, we interpreted the term ''initial preventive physical examination'' for purposes of this benefit to include all of the following service elements:

1. Review of the individual's comprehensive medical and social history, as those terms are defined in proposed § 410.16(a);

2. Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument, which the physician or other qualified NPP may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process;

3. Review of the individual's functional ability and level of safety, as described in proposed § 410.16(a), (that is, at a minimum, a review of the following areas: Hearing impairment, activities of daily living, falls risk, and home safety), based on the use of an appropriate screening instrument, which the physician or other qualified NPP may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is further defined through the NCD process;

4. An examination to include measurement of the individual's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate by the physician or qualified NPP, based on the individual's comprehensive medical and social history and current clinical standards;

5. Performance and interpretation of an electrocardiogram;

6. Education, counseling, and referral, as appropriate, based on the results of the first five elements of the initial preventive physical examination; and

7. Education, counseling, and referral, including a written plan provided to the individual for obtaining the appropriate screening and other preventive services, which are separately covered under Medicare Part B benefits; that is, pneumococcal, influenza, and hepatitis B vaccines and their administration, screening mammography, screening pap smear and screening pelvic examinations, prostate cancer screening tests, colorectal cancer screening tests, diabetes outpatient self-management training services, bone mass measurements, screening for glaucoma, medical nutrition therapy services, cardiovascular (CV) screening blood tests, and diabetes screening tests.

The proposed ''medical history'' definition includes the following elements:

- Past medical history and surgical history, including experience with illnesses, hospital stays, operations, allergies, injuries, and treatment.
- Current medications and supplements, including calcium and vitamins.
- Family history, including a review of medical events in the patient's family, including diseases that may be hereditary or place the individual at risk.

The proposed ''physician'' definition means for purposes of this provision a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

The proposed ''qualified nonphysician practitioner'' for purposes of this provision means a PA, NP, or clinical nurse specialist (CNS) (as authorized under sections 1861(s)(2)(K)(i) and 1861(s)(2)(K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in regulations at § 410.74, § 410.75, and § 410.76).

The proposed ''social history'' definition includes, at a minimum, the following elements:

- History of alcohol, tobacco, and illicit drug use.
- Work and travel history.
- Diet.
- Social activities.
- Physical activities.

The proposed definition of ''Review of the individual's functional ability and level of safety'' includes, at a minimum, a review of the following areas:

- Hearing impairment.
- Activities of daily living.
- Falls risk.
- Home safety.

We also proposed conforming changes to specify an exception to the list of examples of routine physical examinations excluded from coverage in § 411.15(a)(1) and § 411.15(k)(11) for IPPEs that meet the eligibility limitation and the conditions for coverage that we are specifying under § 410.16, Initial preventive physical examinations.

With regards to the issue of payment for the IPPE, in the August 5, 2004 proposed rule we stated that there is no current CPT code that contains the specific elements included in the IPPE and proposed to establish a new HCPCS code to be used for billing for the initial preventive examination. As required by the statute, we indicated that this code includes an electrocardiogram, but does not include the other previously mentioned preventive services that are currently separately covered and paid under the Medicare Part B screening benefits. When these other preventive services are performed, they must be identified using the existing appropriate codes.

Proposed payment for this code was based on the following:

- *Work RVUs:* We proposed a work value of 1.51 RVUs for G0344 (G0XX2 in proposed rule) based on our determination that this new service has equivalent resources and work intensity to those contained in CPT E/M code 99203, *new patient, office or other outpatient visit* (1.34 RVUs), and CPT code 93000 *electrocardiogram, complete* (0.17 RVUs), which is for a routine ECG with the interpretation and report.

- *Malpractice RVUs:* For the malpractice component of G0344, we proposed malpractice RVUs of 0.13 in the nonfacility setting based on the malpractice RVUs currently assigned to CPT code 99203 (0.10) and CPT code 93000 (0.03). In the facility setting, we proposed malpractice RVUs of 0.11 based on the current malpractice RVUs assigned to CPT code 99203 (0.10) and 93010 (an EKG interpretation with a value of 0.01).

- *Practice Expense RVUs:* For the practice expense component of G0344, we proposed practice expense RVUs of 1.65 in the nonfacility setting based on the practice RVUs assigned to CPT code 99203 (1.14) and CPT code 93000 (0.51). In the facility setting, we proposed practice expense RVUs of 0.54 based on the practice expense RVUs assigned to CPT code 99203 (0.48) and 93010 (0.06).

Because some of the components for a medically necessary Evaluation and Management (E/M) visit are reflected in this new G code, we also proposed, when it is appropriate, to allow a medically necessary E/M service no greater than a level 2 to be reported at the same visit as the IPPE. That portion of the visit must be medically necessary to treat the patient's illness or injury or to improve the function of a malformed body member and should be reported with modifier—25. We also stated the physician or qualified NPP could also bill for the screening and other preventive services currently covered and paid by Medicare Part B under separate provisions of section 1861 of the Act, if provided during this IPPE.

The MMA did not make any provision for the waiver of the Medicare coinsurance and Part B deductible for the IPPE. Payment for this service would be applied to the required deductible, which is $110 for CY 2005, if the deductible is not met, and the usual coinsurance provisions would apply.

Analysis of and Response to Comments

We specifically solicited public comments on the definition of the term ''initial preventive physical examination,'' with supporting documentation. For example, we indicated that we chose not to define the term, ''appropriate screening instrument,'' for screening individuals for depression, functional ability, and level of safety, as specified in the rule, because we anticipated that the examining physician or qualified NPP may want to use the test of his or her choice, based on current clinical practice guidelines. We believe that any standardized screening test for depression, functional ability, and level of safety recognized by the American Academy of Family Physicians, the American College of Physicians-American Society of Internal Medicine, the American College of Preventive Medicine, the American Geriatrics Society, the American Psychiatric Association, or the USPSTF, or other recognized medical professional group, would be acceptable for purposes of meeting the ''appropriate screening instrument'' provision. We asked that commenters making specific recommendations on this or any related issue provide documentation from the medical literature, current clinical practice guidelines, or the USPSTF recommendations.

We received 71 public comments on the proposed rule regarding IPPE. Commenters included national and State professional associations, medical societies and medical advocacy groups, hospital associations, hospitals, managed care plans, physicians, senior advocacy groups, health care manufacturers, and others. Although a number of commenters expressed concern that the proposed rule was too prescriptive and not sufficiently targeted to prevention, a large majority of the commenters enthusiastically supported most of the coverage provisions of the proposed rule. Many of the commenters, however, suggested clarification and revision of the rule in a number of different areas, including the proposed definitions of ''initial preventive physical examination,'' ''physician,'' and ''qualified nonphysician practitioner.'' Commenters also raised questions regarding other issues, such as those relating to the need for us to educate Medicare beneficiaries and providers with respect to the new benefit, and to monitor the implementation of the new benefit. Finally, commenters offered suggestions and questions with regards to payment issues, evaluation and

management services (E/M) and coinsurance and Part B deductible issues.

A summary of the comments and our responses are presented below.

Comment: A number of commenters expressed concern that in the proposed rule, we had gone beyond the coverage criteria that were specified in the statute for the new benefit. They noted that the additional criteria was too prescriptive and would only add confusion and an additional burden for physicians in determining what medical services are necessary for each beneficiary they evaluate. Several commenters indicated that while the proposed definition for the scope of the benefit was well-intentioned, the beneficiary's physician or other provider was the best person to determine what medical services are necessary in providing a thorough physical and to be responsive to the individual's age, gender, and particular health risks. In general, they suggested that we not interfere in a physician's judgment by attempting to standardize by Federal regulations the specific medical services to be included under the new benefit.

Response: Section 611 of the MMA defines the scope of the IPPE benefit as physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure and an electrocardiogram) with the goal of health promotion and disease detection, as well as certain education, counseling, and referral services with respect to other statutory screening and preventive services also covered under the Medicare statute. We believe that the statutory parenthetical language, (including measurement of height, weight, and blood pressure and an electrocardiogram) recognizes that other services could be contained within the IPPE benefit. We are using the authority under section 1871(a) of the Act through the rulemaking process to provide clarity as to the specific services that are to be included under the new benefit.

We believe that adding these additional services will help to ensure that a full and complete IPPE is provided to each beneficiary who chooses to take advantage of the service and that all beneficiaries who decide to do this are treated in a relatively uniform manner throughout the country. With an estimated 200,000 individuals expected to enroll in Medicare Part B each month starting in January 2005, who will be eligible to receive the IPPE benefit, we believe that it is paramount that we promulgate a minimum list of required services important to the goals of health promotion and disease detection that must be included in the new benefit, and we are specifying those service elements in the final rule.

The ''Initial Preventive Physical Examination'' Definition (IPPE) (§ 410.16(a))

Comment: Three commenters indicated that this new benefit presents a unique opportunity to offer Medicare beneficiaries with a visit focused on prevention at the start of their Part B enrollment. They suggested, that we shift our focus in service element 1 of the definition of the new IPPE from a comprehensive to a more targeted priority list of modifiable risk factors, screening tests, and immunizations that are supported by the strongest evidence of effectiveness, and have been proven to improve the health of beneficiaries.

Response: We agree that the intent of the new benefit is to deliver clinical preventive services that are accepted and effective in helping to keep people healthy and reduce the burden of disease whenever possible. Therefore, we agree to revise the language in service element 1 to read as follows: ''Review of the individual's medical and social history with particular attention to modifiable risk factors for disease.''

Comment: Three commenters indicated that the collection of information on a beneficiary's social history such as social activities, work and travel history, is a distraction and is not needed by the physician or other qualified NPP who is performing the preventive physical examination. The commenters suggest that we eliminate the proposed definition and not require the collection of this information.

Response: We agree that information on work and travel history, and social activities may not be necessary for purposes of the new preventive physical examination and thus we are removing those elements from the minimum requirements for the ''social history'' definition. However, we believe it is important to retain three elements of the Social history definition in the final rule and they will be reflected in that document as follows:

- History of alcohol, tobacco, and illicit drug use.
- Diet.
- Physical activities.

Comment: Several commenters requested that we add language to service element 1 to allow practitioners to ascertain information from individuals about additional disease or other diagnoses such as including questions regarding past diagnoses or treatment of cancer, diabetes, elevated blood sugar, height loss, previous fractures, and medical conditions that may increase a person's risk of coagulopathic disorders such as deep venous thrombosis (DVT).

Response: In applying our definition of ''past medical history'' we expect that physicians and qualified NPPs performing the IPPE will be able to ask about an array of medical illnesses, including prior diagnoses and treatment of conditions such as cancer, diabetes, risk factors for osteoporosis such as height loss or previous fractures, and history of coagulopathic disorders such as DVT. Therefore, we do not see a need to expand the proposed definition as the commenters have suggested, and we have decided to leave it unchanged in the final rule.

Comment: Three commenters asked us to add language to either service element 1 or 3 to allow practitioners to screen individuals for memory impairment.

Response: Currently, the USPSTF has found insufficient evidence to recommend for or against routine screening for dementia with standardized instruments in asymptomatic persons. However, the USPSTF notes that patients with problems in performing daily activities should have their mental status evaluated and clinicians should remain alert for possible signs of declining cognitive function. We included as part of the definition for service element 3, ''Review of the individual's functional ability and level of safety,'' a review of the patient's activities of daily living. While not exhaustive, this review will primarily aid physicians in identifying a patient's problems with regard to performing these activities and the role cognitive impairment may play in these deficits.

Comment: One commenter proposed that we not use the NCD process to revise the content of the IPPE in the future. The NCD process would be too slow or cumbersome to allow us to keep the content of the examination consistent with current clinical practice.

Response: For service elements 2 and 3, which discuss the future use of the NCD process in determining appropriate screening instruments we will delete the following: ''unless the appropriate instrument is defined through the NCD process.'' We will add language that states available standardized screening tests must be recognized by national medical professional organizations.

Comment: Several commenters requested that we clarify our intent as to whether the depression screening assessment in service element 2 will include consideration of the potential for depression as well as an assessment

of an individual's current depression status. Another commenter asked us to clarify our intent with respect to the use of a screening instrument for persons with a current diagnosis of depression.

Response: We agree with the commenters that the regulation language on depression screening needs to be clarified. We are revising service element 2 to read ''review of the individual's potential (risk factors) for depression, including current or past experience with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.''

Comment: Three commenters expressed the view that the proposed screening tests for falls risk and home safety in service element 3 were not supported by direct scientific evidence, and should be dropped from the IPPE benefit in the final rule.

Response: Falls are among the most common and serious problems facing elderly persons. They are associated with considerable morbidity such as hip fractures and overall reduced level of functioning. The USPSTF also notes that falls are the second leading cause of unintentional injury deaths in the United States. The death rate due to falls increases as a person ages. According to the National Center for Injury Prevention and Control, approximately one-half to two-thirds of all falls occur in and around a person's home. Therefore, discussing with patients home safety tips may reduce some home hazards. In addition, the USPSTF recommends counseling patients on specific measures to reduce the risk of falling, although direct evidence of effectiveness has not yet been established. Therefore, we believe that questioning and counseling patients to determine their risk of falling and home safety is warranted as part of the IPPE benefit.

Comment: Several commenters from the audiology community have asked us to clarify the meaning of the proposed requirement in service element 3, which includes (among other things) a review of any hearing impairment. In addition, several commenters have requested that we clarify whether a hearing assessment is required as part of service element 3, or whether questions (or a questionnaire) advanced to an individual about any possible hearing problems would suffice for purposes of this part of the new benefit. The commenters ask for provider flexibility in meeting this requirement.

Response: The regulatory intent of service element 3 is that we expect that the physician or qualified NPP will engage in a dialogue with patients concerning these issues by asking the individual appropriate questions or using a written questionnaire to address hearing impairment, activities of daily living, falls risk, and home safety. We do not intend for actual screening instruments such as audiometric screening tests to be used. After questioning the individual, if abnormalities are identified, additional follow-up services may be warranted and may include education, counseling, and referral (if appropriate.)

Therefore, we are revising the language of service element 3 to read ''review of the individual's functional ability and level of safety, based on the use of appropriate screening questions or a screening questionnaire which the physician or qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national medical professional organizations.''

Medically necessary diagnostic hearing tests, including hearing and balance assessment services, performed by a qualified audiologist are covered as other diagnostic tests under section 1861(s)(3) of the Act and would be separate from the new IPPE benefit. These services may be appropriate when a physician or other qualified NPP orders a diagnostic hearing test for the purpose of obtaining information necessary for the physician's diagnostic evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem. However, coverage of this testing is excluded by virtue of section 1862 (a)(7) of the Act when the diagnostic information required to determine the appropriate medical or surgical arrangement is already known to the physician, or the diagnostic services are performed only to determine the need for the appropriate type of hearing aid. For further information about the application of the hearing test exclusion to diagnostic hearing tests and payment for these services, we suggest review of section 80.3 to 80.3.1 of the Medicare Benefit Policy Manual.

Comment: Several commenters suggested that we expand the services to be included as part of service element 4 that was proposed for coverage under the IPPE benefit to include: (1) Palpitation/auscultation of carotid arteries; (2) palpitation/auscultation of abdominal aorta; and (3) the ankle-brachial index (ABI) test for peripheral arterial disease (PAD).

Response: Currently, routine screening of asymptomatic persons for carotid artery stenosis via palpation/auscultation of the carotid arteries or carotid ultrasound is not recommended by organizations such as the USPSTF, which provides guidelines on this issue. Therefore, we are not adding routine screening of asymptomatic individuals for carotid artery stenosis to service element 4 in the absence of evidence of the effectiveness of the screening. In addition, the USPSTF has determined that there is insufficient evidence to recommend for or against routine screening of asymptomatic adults for abdominal aortic aneurysm (AAA) by palpation/auscultation or ultrasound of the abdominal aorta so we are not adding that type of screening to service element 4.

Finally, the USPSTF does not recommend routine screening for PAD in asymptomatic persons. However, they also state that clinicians, should be aware of symptoms and risk factors for PAD and evaluate patients accordingly. Therefore, routine screening for PAD with the use of the ABI will not be required as part of the initial preventive physical examination.

Comment: One commenter asked for clarification on whether the proposed regulatory language ''and other factors deemed appropriate by the physician or qualified nonphysician practitioner,'' as specified in service element 4, would permit inclusion of coverage of a screening for chronic obstructive pulmonary disease (COPD) through spirometric testing under the IPPE benefit.

Response: The intent of this language for the actual physical examination portion of the IPPE benefit is to leave to the discretion of the physician or other qualified NPP whether to perform commonly utilized physical examination measures such as auscultation of the heart or lungs on a particular patient, if needed. Spirometry as a screening test for COPD, however, would not be considered to fall within the scope of the physical examination element of the IPPE benefit.

Comment: A number of commenters suggested that we add an assessment of abdominal obesity or alternatively the calculation of the body mass index (BMI) to the vital signs part of service element 4 to help in determining if an individual is at risk for a heart attack, diabetes, or other medical problems.

Response: By requiring measurement of height and weight as part of the IPPE in element 4 (an examination to include

measurement of an individual's height, weight, blood pressure), we believe that the physician or other qualified NPP performing the IPPE will use that information to determine an individual's BMI if necessary.

Comment: Three commenters expressed concern about the wide latitude given to physicians and other qualified NPPs providing the IPPE benefit to select whichever screening test they prefer to use in connection with the assessment of visual acuity. The commenters believe that setting vague boundaries around what constitutes an appropriate screening instrument could open the door for inappropriate use of preventive services. To avoid this, the commenters recommend narrowly defining the appropriate screening instrument for visual acuity in service element 4 by specifying the use of the Snellen test for that purpose.

Response: We agree that the Snellen test is a widely available test used to assess a person's visual acuity. Other similarly available tests for visual acuity also exist, however, and may convey similar results for individual physicians and other clinicians. While we expect that many physicians will utilize the Snellen test in assessing a beneficiary's visual acuity for the purpose of this new benefit, we are not mandating the use of the Snellen test or any other specific visual acuity test in order to meet the requirements of element 4 in the final rule.

Comment: One commenter noted that the proposed rule allows for coverage of the assessment in service element 4 of ''other factors as deemed appropriate based on the individual's comprehensive medical and social history.'' The commenter expressed the view that the quoted language might result in the possibility that virtually any patient's abnormality identified during the preventive physical examination might lead to further evaluation of the patient and a cascade of diagnostic workup of questionable health benefit to the patient and potentially of great cost to the Medicare program. In view of these concerns, the commenter recommended using more restrictive language that would allow for additional assessment of other factors only when they are supported by evidence-based clinical practice guidelines.

Response: Our purpose in proposing the specific quoted language referenced in service element 4 was to allow for the physician or other qualified NPP to perform a limited physical examination of those key elements such as height, weight, blood pressure, and a visual acuity screen that may be important in detecting disease. However, we have specified that additional physical examination measures may be performed if deemed appropriate based on the issues identified by the physician or other clinician in the review of service elements 1 to 3. While we will not specify in the final rule that these additional measures must be supported by evidence-based practice guidelines, we will state that the practitioner performing the preventive examination follow current clinical standards and those guidelines, of course, may include the evidence-based guidelines referenced by the commenter.

Comment: One commenter recommends that we include in our guidelines for the IPPE benefit information that informs the physician or other qualified NPP of: (1) The need to refer patients to occupational therapists when a more extensive evaluation of activities of daily living, falls risk, and home safety is warranted; and, (2) when, such referrals would be medically appropriate.

Response: As part of the final rule, service element 6 of the IPPE benefit will require, education, counseling, and referral, as appropriate, based on the individual's results of the previous 5 elements of the IPPE benefit. However, appropriate referral of a patient to an occupational therapist is left to the discretion of the physician or other qualified NPP who is treating the patient for the medical problem that is identified, subject to contractors' medical necessity review. We do not believe there is a need for us to issue guidelines to our contractors on this point.

Comment: Several commenters indicated that they were concerned about use of the term ''counseling'' in service elements 6 and 7 of the definition of the IPPE because it lacked sufficient clarity. The commenters indicated that counseling may include varying amounts of time depending upon the intensity of the type of service provided, the ability of the individual receiving the counseling to understand the information that is being communicated, etc. The commenters suggested that either we not use the term counseling or clarify its meaning in the final rule.

Response: Use of the term counseling in connection with service element 7 is mandated by section 611 of the MMA, and thus, it is appropriate to use the term in the final rule. However, we would like to clarify this issue in connection with both service elements 6 and 7 of the new benefit. In most cases, we do not expect that the physician or other qualified NPP performing the service should need to spend more than a few minutes of brief education and counseling with a new beneficiary on appropriate topics as required by element 7. Nonetheless, it is possible that it may be necessary to spend more than a few minutes on the education and counseling required by element 6. As the commenters have indicated, the education and counseling required may involve varying amounts of time depending upon the medical problem or problems that are being considered, based on the results of elements 1 to 5, and the intensity of the service that is believed to be medically necessary at that time.

Comment: Three commenters indicated that they support proposed service element 6 on ''education, referral, and counseling deemed appropriate based on the results of the review and evaluation of services,'' in service elements 1 to 5 because it offers an unprecedented opportunity to counsel beneficiaries about health behaviors (for example, stopping smoking, losing weight). Nonetheless, they were concerned about possible over-utilization of services that might result from that provision, and suggest that we clarify that these education, counseling and referral efforts be concordant with evidence-based practice guidelines.

Response: We will not specify in the final rule that education, counseling, and referral efforts must be consistent with evidence-based practice guidelines. We expect that physicians and other qualified NPPs will provide appropriate education, counseling, and referral that utilizes evidence-based practice guidelines and current clinical standards. In addition, follow-up care obtained outside of the IPPE Benefit must be reasonable and necessary based on Section 1862(a)(1)(A) of the Act.

Comment: A number of commenters requested that we clarify the written plan provision of service element 7 that was included in the proposed rule. Several commenters indicated that two problems they see with this requirement are: (1) It is not clearly defined and thus could impose a significant burden on physicians and other clinicians, if it is not more carefully written; and, (2) it does not acknowledge that alternative mechanisms may already be in place that could better facilitate coordination of care for these beneficiaries than the proposed written plan requirement. For example, one commenter suggests that some physicians and other clinicians may currently be using electronic technology to track the delivery of preventive services and should not be

required to file written plans. Instead, the commenter recommends that we craft language to require physicians to demonstrate a system for ensuring that beneficiaries receive recommended screening and preventive services and allow physicians flexibility to determine the design and medium that such a system would employ.

Response: We agree that the term written plan may not offer a sufficiently clear description of our intentions in requiring the physician or other qualified NPP who also performs the IPPE to carry out the statutory mandate that eligible beneficiaries be provided with education, counseling, and referral for screening and other preventive services described in section 1861(ww)(2) of the Act. Our intent in the proposed rule was that each physician or other qualified NPP provide their eligible beneficiaries at the time of the examination with appropriate education, counseling, and referral(s), including a brief written plan such as a checklist, which is provided to the beneficiary for obtaining the appropriate screening and/or other preventive services that are covered as separate Medicare Part B benefits to which he or she is entitled. We acknowledge that physicians or qualified NPPs may have an alternative mechanism in place to ensure that beneficiaries receive recommended screening and other preventive services that does not provide for a written plan to be provided to the beneficiary. However, the intent of the written plan requirement is to promote and encourage beneficiary participation in the health care process by making them aware, briefly in writing of the screening and prevention services for which they are entitled under the Medicare Part B program.

In conclusion, we will revise service element 7 to read ''education, counseling, and referral, including a brief written plan such as a checklist, be provided to the individual for obtaining appropriate screening and other preventive services, which are separately covered under Medicare Part B benefits.''

The ''Physician'' Definition (§ 410.16(a))

Comment: One commenter expressed concerns regarding the definition of a physician. The commenter expressed concern that the proposed rule limits the type of practitioner who is considered qualified to perform the new preventive physical examination. The commenter states that this restriction was not specified by the Congress in section 611 of the MMA or its accompanying conference committee report, and suggests that it should be revised to allow all practitioners, including doctors of podiatric medicine, who are defined as a physician under section 1861(r) of the Act, to be considered qualified to perform the preventive physical examination.

Response: Section 611 of the MMA amended the statute to provide that payment for the IPPE must be made under the Medicare physician fee schedule, as provided in section 1848(j)(3) of the Act, but it did not specifically define what type of physician is eligible for performing this examination. In developing the proposed rule on which physicians are considered qualified to perform the IPPE, we considered the various types of physicians that are identified in section 1861(r)(2), (r)(3), (r)(4), and (r)(5) of the Act. These include doctors of dental surgery, doctors of podiatric medicine, doctors of optometry, and chiropractors, whose scope of medical practice is generally limited by State law to a particular part (or parts) of the human anatomy.

These state licensing restrictions would likely make it difficult for those practitioners to perform all of the services required. Based on this information, we are leaving the definition of a physician unchanged in the final rule.

The ''Qualified Nonphysician Practitioner'' Definition (§ 410.16(a))

Comment: One commenter indicated concern that in the proposed rule certified nurse-midwives (CNMs) are not eligible to furnish the new preventive physical examinations, but physicians and certain other NPPs are eligible to provide those services to Medicare beneficiaries. The commenter indicates that CNMs are fully qualified to provide physical examination and checkups covered by the statute and that they do so on a daily basis as a basic component of the care they provide their clients. The commenter states that we may be constrained by the statute as enacted by Congress on this subject, but suggests that we should review the issue and if possible revise the proposed rule to include CNMs among those who are considered to be eligible to provide the new service in the final rule.

Response: Section 611 of the MMA amended the statute to provide that in addition to physicians certain NPPs, that is, PAs, NPs, and CNS (as authorized under section 1861(s)(2)(K)(i) and (ii) of the Act, and defined in section 1861(aa)(5) of the Act, or in regulations at § 410.74, § 410.75, and § 410.76) will be able to furnish the new preventive physical examination to eligible beneficiaries effective January 1, 2005. Thus, Congress did not specifically authorize CNMs to perform the IPPE. Unless CNMs are able to qualify as one of these other types of NPPs designated by the statute for purposes of the new IPPE benefit, they will not be eligible to provide this service to beneficiaries for Medicare Part B coverage purposes.

Other Issues

Comment: One commenter requested that we clarify application of the proposed IPPE definition to managed care plans where preventive physical examinations are available to Medicare enrollees on an annual basis and they are not limited to a one-time benefit. Generally in the case of managed care plans, it is indicated that the extent of their typical annual preventive examination is determined by the enrollee's physician or other treating physician, depending upon the patient's history and clinical indications. The commenter asks that we allow managed care plans greater flexibility in providing their Medicare enrollees with the various service elements described in the proposed rule. Alternatively, the commenter requests that we clarify in the final rule that managed care plans will need to provide their Medicare enrollees with all elements of the new benefit only if requested to do so by a particular Medicare enrollee.

Response: Section 611 of the MMA requires that IPPEs be made available to all Medicare beneficiaries who first enroll in Medicare Part B on or after January 1, 2005, and who receive that benefit within 6 months of the effective date of their initial Part B coverage period. The new statute does not allow for any exceptions to be made to the coverage of IPPEs for beneficiaries who are members of managed care plans. In fact, section 1852(a) of the Act provides that generally each managed care plan must, at a minimum, provide to its Medicare members all of those items and services (other than hospice care) for which benefits are available under Parts A and B for individuals residing in the area served by the plan. Nonetheless, if a particular Part B member of the plan chooses not to take advantage of the IPPE benefit, for example, because it would duplicate an annual preventive physical exam that has already been provided to that member, the plan would not be obligated to provide the IPPE to that member.

Comment: One commenter noted that while the screening benefits listed in paragraph (A)(1) on **Federal Register**

page 47514 (vol. 69, No. 150) includes ''(5) colorectal cancer screening test,'' the list of screening benefits described in the same section, paragraph (7) on page 47515 does not include that type of cancer screening test. The commenter requests that we include colorectal cancer screening in the list of screening services described on page 47515 of the Physician Fee Schedule Proposed Rule and any other sections of any proposed rule in which covered screening benefits are listed to ensure there is no confusion regarding what services should discussed with patients during the IPPE.

Response: We agree with the commenter that there was an error of omission relative to colorectal cancer screening in the language in the preamble to the proposed rule in the list of screening benefits described on page 47515 of the Physicians Fee Schedule, and we have corrected that oversight in this final rule.

Comment: One commenter requests that we clarify the part of the definition of the IPPE (service element 7) that refers to the provision of education, counseling, and referral of the individual for coverage of bone mass measurements by adding the term ''Dual Energy X–Ray Absorptiometry'' (DEXA) to that provision. The commenter states that DEXA testing is the most accurate method available for diagnosis of osteoporosis and that early detection of this condition paramount for preventing further bone loss and eventual fractures. The commenter is concerned that unless this is clarified in the final rule, local Medicare contractors may exclude coverage for the DEXA test as part of the IPPE benefit.

Response: Our existing regulations governing bone mass measurements are published in § 410.31. While we agree that the DEXA scan is a very commonly used method for the initial diagnosis of osteoporosis, we do not believe that it would be appropriate to add any specific reference to the DEXA test in the IPPE definition because it may be perceived as endorsing one test over another. We do not believe this would be appropriate. Physicians and other qualified NPPs who perform IPPE services may provide appropriate education, counseling, and referral of their Medicare patients for the bone density tests. The counseling and referral may include choosing the appropriateness of the diagnostic modalities for the particular patient.

Comment: A number of commenters have asked us to provide information to Medicare physicians and qualified NPPs performing the IPPE for appropriate referral of their patients when treatment or a more extensive evaluation of patients is needed as part of service element 6.

Response: As part of the final rule, under service element 6, providers are required to furnish their patients with education, counseling, and referral, as appropriate, based on the individual's results of service elements 1–5 of the IPPE service. However, appropriate referral of a patient, of course, is left to the discretion of the physician or other qualified NPP who is treating the patient for the medical problem that is identified.

Comment: One commenter asked us how we plan to monitor the effectiveness of the IPPE benefit over the next several years.

Response: As indicated in the final rule, we have established unique billing codes for the IPPE service which physicians and other qualified NPPs must use in billing Medicare Part B for the new service. Establishing those codes will allow us to monitor over time the extent to which the eligible Medicare Part B population is utilizing the new service, which will be of interest to our program administrators, members of the Congress, and the general public.

Comment: One commenter asked how providers of IPPE services will know if a particular beneficiary is eligible to receive the new benefit due to the statutory time and coverage frequency (one-time benefit) limitations.

Response: The statute provides for coverage of a one-time IPPE benefit that must be performed for new beneficiaries by qualified physicians or certain specified NPPs within the first 6 months period following the effective date of the beneficiary's first Part B coverage. Since physicians or other qualified NPPs may not have the complete medical history for a particular new beneficiary, including information on possible use of the one-time benefit, these clinicians are largely relying on their own medical records and the information the beneficiary provides to them in establishing whether or not the IPPE benefit is still available to a particular individual and was not performed by another qualified practitioner. Since a second IPPE will always fall outside the definition of the new Medicare benefit, an advance beneficiary notice (ABN) need not be issued in those instances where there is doubt regarding whether the beneficiary has previously received an IPPE. The beneficiary will always be liable for a second IPPE no matter when it is conducted. However, for those instances where there is sufficient doubt as to whether the statutory 6-month period has lapsed, the physician or other qualified NPP should issue an ABN indicating that Medicare may not cover and pay for the service. If the physician or other qualified NPP does not issue an ABN and Medicare denies payment because the statutory time limitation for conducting the initial IPPE has expired, then the physician or other qualified NPP may be held financially liable.

Comment: Several commenters asked that we provide explicit instructions and guidelines, respectively, to providers and beneficiaries regarding the details of what will be included in the new benefit, the eligibility requirements, and how providers must bill Medicare for the new service.

Response: Medicare will release appropriate manual and transmittal instructions and information from our educational components for the medical community, including a MedLearn Matters article and fact sheets like the ''2005 Payment Changes for Physicians and Other Providers: Key News From Medicare for 2005''. The medical community can join this effort in educating physicians, qualified NPPs, and beneficiaries by distributing their own communications, bulletins or other publications.

In addition, we have specifically included information on the new IPPE benefit in the 2005 version of the *Medicare and You Handbook* and the revised booklet, *Medicare's Preventive Services.* A new 2-page fact sheet on all of the new preventive services, including the IPPE benefit, is currently under development, and a bilingual brochure for Hispanic beneficiaries will also be available in the new future. This information will be disseminated by our regional offices, State Health Insurance Assistance Programs (SHIPs), and various partners at the national, State, and local levels. Information on the new benefit will also be made available to the public through medicare.gov, the cms.gov partner Web site, 1–800–MEDICARE, numerous forums hosted by CMS, and conference exhibits and presentations.

Comment: Many of the major physician specialty societies believe the payment, as proposed, is undervalued for what is believed to be a labor-intensive IPPE. They request that we use the existing CPT preventive medicine services code series rather than creating a new G-code. These codes have higher RVUs than the office or other outpatient visit code 99203. For example, preventive medicine services visit code 99387 has total nonfacility RVUs of 4.00 while the corresponding value for 99203 is 2.58.

Response: The existing CPT preventive medicine services codes

(99381–99397) are not covered by Medicare. In accordance with section 1862(a)(1)(A) of the Act that requires us to pay only for services that are reasonable and necessary for the treatment of an illness or injury or to improve the function of a malformed body member, we have not covered E/M visits for screening purposes.

The IPPE is intended to target selected modifiable risk factors and secondary prevention opportunities shown by evidence to improve the health and welfare of the beneficiary, and is less focused on a comprehensive physical examination compared to the typical service provided in accordance with CPT code 99397. We equated the resources anticipated with this service to the existing new office or other outpatient visit. For CPT code 99203 the RUC survey data shows 53 physician minutes (including pre-service time, intra-service time and post-service time) with 51 minutes of staff time. We believe the IPPE will reflect these time approximations. We will be looking at the data and consulting with the medical community after initial experience with this new benefit to determine if this payment has been valued appropriately.

Comment: Two commenters suggested that we allow the IPPE either on a yearly basis or every decade after the initial evaluation.

Response: The IPPE was specifically legislated as a one time only benefit for the beneficiary newly enrolled in the Medicare program. This visit familiarizes the beneficiary with a physician or qualified NPP who will highlight the assessments available to help prevent and detect disease and also make available the educational, counseling and referral opportunities to the new Medicare recipient. Our policy anticipates physicians will make appropriate and individualized referrals for the beneficiary. Expanding the number of routine physicals would require additional legislation (See section 1862(a)(7) of the Act).

Comment: Many commenters asked if the IPPE may be provided without performing the EKG at the same visit. They asked to have the EKG component unbundled from the evaluation and management component that had been specified in the proposed rule for the IPPE service since a physician may not have the equipment and capability of providing EKG services to their patients in the office suite or clinic. Additionally, others asked if a physician would be denied payment for the IPPE if the screening EKG was not performed because a diagnostic EKG was performed in a recent visit or if a diagnostic EKG was warranted at the IPPE visit.

Response: Section 611 of the MMA does require a screening EKG to be performed as part of the IPPE visit. We recognize that there are a number of primary care physicians or other clinicians furnishing the service who may want to refer their beneficiaries to outside practitioners or entities for performance and interpretation of the EKG service rather than performing it themselves. Therefore, if an individual physician or other qualified NPP does not have the capacity to perform the EKG in the office suite, then alternative arrangements will need to be made with an outside physician or other entity in order to make certain that the EKG is performed. In circumstances where the primary care physician or qualified NPP refers the beneficiary to an outside physician or entity for the EKG service, we expect that the primary care physician or qualified NPP will incorporate the results of the EKG into the beneficiary's medical record to complete the IPPE. Both components of the IPPE, the examination portion and the EKG, must be performed for either of the components to be paid. Billing instructions for physicians, qualified NPPs and providers will be issued. In order to address these potentially occurring scenarios to complete the IPPE and EKG we have created the following HCPCS codes:

- G0344: *Initial preventive physical examination; face-to-face visit services limited to new beneficiary during the first six months of Medicare enrollment*
- G0366: *Electrocardiogram, routine ECG with at least 12 leads with interpretation and report, performed as a component of the initial preventive physical examination*

A physician or qualified NPP performing the complete service would report both G0344 and G0366.

- G0367: *tracing only, without interpretation and report, performed as a component of the initial preventive physical examination*
- G0368: *interpretation and report only, performed as a component of the IPPE*

RVUs for payment for these new HCPCS codes will be crosswalked from the following CPT codes:

- G0344 will crosswalk from CPT code 99203 *(Office or other outpatient visit)*
- G0366 will crosswalk from CPT code 93000 *(Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report)*
- G0367 will crosswalk from CPT code 93005 *(Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report)*
- G0368 will crosswalk from CPT code 93010 *(Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only)*

Note that HCPCS codes G0366 and G0367 are not payable under the physician fee schedule in the facility setting.

To comply with MMA the IPPE must include the EKG regardless of whether a diagnostic EKG was recently performed. An EKG performed by the physician or qualified NPP during the IPPE visit must be reported with HCPCS code G0366. Medicare does not cover a screening EKG alone.

Comment: One commenter asked if physicians and qualified NPP who see patients in Federally Qualified Healthcare Centers (FQHCs) will be able to provide and bill under the FQHC all-inclusive rate.

Response: Physicians and other qualified NPPs in RHCs and FQHCs may provide this new benefit and follow normal procedures for billing for RHCs and FQHC services. Payment for the professional services will be made under the all-inclusive rate.

Comment: Many physician specialty societies did not agree with our proposal to limit the level of a medically necessary E/M visit when performed and billed with the IPPE. They contend that most Medicare patients, even if known to their physician, come to the IPPE visit with multiple chronic problems often necessitating immediate evaluation and treatment at a level of care equal to a level 4/5 E/M visit code. They also state that current Medicare policy does permit a medically necessary E/M visit at whatever level is appropriate when the noncovered preventive medicine services (CPT codes 99381–99397) are performed. They ask that we eliminate the restriction for the level of service for a medically necessary E/M visit performed at the same visit as the IPPE visit.

Response: The physician will need to schedule time with the beneficiary identifying the available preventive and educational opportunities. A level 2 new or established patient office or other outpatient visit code was proposed because we believe there is a substantial overlap of practice expense, malpractice expense and physician work in both history taking and examination of the patient with the IPPE and another E/M service. We do not want to prohibit the use of an appropriate level of service when it is necessary to evaluate and treat the beneficiary for acute and chronic

conditions. At the same time, we believe the physician is better able to discuss health promotion, disease prevention and the educational opportunities available with the beneficiary when the health status is stabilized and the beneficiary is physically receptive.

We will remove the restriction limiting the medically necessary E/M service to a level 2 visit code. CPT codes 99201 through 99215 may be used depending on the circumstances and appended with CPT modifier ''25 identifying the E/M visit as a separately identifiable service from the IPPE code G0344 reported.

We do not believe this scenario will be the typical occurrence and, therefore, we will monitor utilization patterns for the level 4/5 new or established office or other outpatient visit codes being reported with the IPPE. If there are consistent data that demonstrate high usage of level 4/5 E/M codes we may need to revise the policy.

Comment: Two commenters asked if we would permit separate payment for a digital rectal exam (DRE) when performed on the same day as the initial preventive physical examination.

Response: Currently Medicare does not make separate payment for DRE (code G0102) when performed on the same day as an E/M service. We will maintain the current policy and not pay separately for a DRE performed during the IPPE visit. A DRE is usually furnished as part of an E/M service and is bundled into the payment for an E/M service when a covered E/M service is furnished on the same day as a DRE. It is a relatively quick and simple procedure and if it is the only service furnished or is provided as part of an otherwise noncovered service it would be payable if coverage requirements are met.

Comment: Several commenters requested guidance on documentation.

Response: It is expected that the physician will use the appropriate screening tools. As for all E/M services, the 1995 and 1997 E/M documentation guidelines must be followed for recording information in the patient's medical record. The screening tools used, EKG documentation, referrals and a written plan for the patient also must be included in the patient's medical record. These forms and methods of documentation mirror those that would be used in typical physician practice with patient visits and do not add an additional burden to the physician.

Comment: Several commenters expressed concern that the non-waived deductible and coinsurance will be a disincentive to the beneficiary having the IPPE. They are concerned that some beneficiaries will not avail themselves of the opportunity of the IPPE visit because of the beneficiary's cost share.

Response: The MMA did not waive the deductible and coinsurance, therefore, we must implement the provision as written.

Result of Evaluation of Comments

In view of the comments, we have decided to make several revisions in § 410.16(a) relative to service elements 1, 2, and 3. We are revising § 410.16(a)(1)(i) language in service element 1 to read as follows: ''Review of the individual's medical and social history with particular attention to modifiable risk factors for disease.''

We are clarifying the regulation language on depression screening (service element 2) by revising § 410.16(a)(1)(ii) to specify that review of the individual's potential (risk factors) for depression, including current or past experience with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations. To allow for a certain amount of provider flexibility in meeting the requirements of the regulatory intent of service component 3 we are revising § 410.16(a)(1)(iii) to specify that review of the individual's functional ability and level of safety, based on the use of appropriate screening questions or a screening questionnaire, which the physician or qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national medical professional organizations.

To clarify the requirements of the regulatory intent of service component 7 we are revising § 410.16(a)(1)(vii) to specify that education, counseling, and referral, including a brief written plan such as a checklist be provided to the individual for obtaining the screening and other preventive services for the individual that are covered as separate Medicare Part B benefits.

The ''social history'' definition in the final rule will be revised to include 3 elements:

- History of alcohol, tobacco, and illicit drug use.
- Diet.
- Physical activities.

With regard to payment of the IPPE, we will use the new HCPCS codes and payment will be based on the RVUs of the CPT codes crosswalked as stated above. We will not finalize our proposal to allow a medically necessary E/M service no greater than a level 2 to be reported at the same visit as the IPPE.

B. Section 613—Diabetes Screening

Section 613 of the MMA adds section 1861(yy) to the Act and mandates coverage of diabetes screening tests.

The term ''diabetes screening tests'' is defined in section 613 of the MMA as testing furnished to an individual at risk for diabetes and includes a fasting blood glucose test and other tests. The Secretary may modify these tests, when appropriate, as the result of consultations with the appropriate organizations. In compliance with this directive, we consulted with the American Diabetes Association, the American Association of Clinical Endocrinologists, and the National Institute for Diabetes and Digestive and Kidney Diseases.

1. Coverage

We proposed in § 410.18 that Medicare cover—

- A fasting blood glucose test; and
- Post-glucose challenge tests; either an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, or a 2-hour post-glucose challenge test alone.

We would not include a random serum or plasma glucose for persons with symptoms of uncontrolled diabetes such as excessive thirst or frequent urination in this benefit because it is already covered as a diagnostic service. This language is not intended to exclude other post-glucose challenge tests that may be developed in the future, including panels that may be created to include new diabetes and lipid screening tests. We also would include language that would allow Medicare to cover other diabetes screening tests, subject to a NCD process.

The statutory provision describes an ''individual at risk for diabetes'' as having any of the following risk factors:

- Hypertension.
- Dyslipidemia.
- Obesity, defined as a body mass index greater than or equal to 30 kg/m2.
- Previous identification of an elevated impaired fasting glucose.
- Previous identification of impaired glucose tolerance.
- A risk factor consisting of at least two of the following characteristics:

+ Overweight, defined as a body mass index greater than 25 kg/m2, but less than 30.

+ A family history of diabetes.

+ A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

+ 65 years of age or older.

For individuals previously diagnosed as diabetic, there is no coverage under this statute.

The statutory language directs the Secretary to establish standards regarding the frequency of diabetes screening tests that will be covered and limits the frequency to no more than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

We proposed that Medicare beneficiaries diagnosed with pre-diabetes be eligible for the maximum frequency allowed by the statute, that is, 2 screening tests per 12 month period. We defined ''pre-diabetes'' as a previous fasting glucose level of 100–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL. This definition of pre-diabetes was developed with the assistance of the American Association of Clinical Endocrinologists, concurs with the Centers for Disease Control and Prevention (CDC) definition, and complements the definition of diabetes that we published November 7, 2003 (68 FR 63195).

2. Payment

We proposed to pay for diabetes screening tests at the same amounts paid for these tests when performed to diagnose an individual with signs and symptoms of diabetes. We would pay for these tests under the clinical laboratory fee schedule. We proposed to pay for these tests under CPT code 82947 Glucose; quantitative, blood (except reagent strip), CPT code 82950, post glucose dose (includes glucose), and CPT code 82951 Glucose; tolerance test (GTT), three specimens (includes glucose). To indicate that the purpose of the test is for diabetes screening, we would require that the laboratory include a screening diagnosis code in the diagnosis section of the claim. We proposed V77.1 special screening for diabetes mellitus as the applicable ICD–9–CM code for this purpose. Because laboratories are required and accustomed to submitting diagnosis codes when requesting payment for testing, we believe including a screening diagnosis code is appropriate for this benefit.

Comment: One commenter questioned whether there is statutory authority to expand eligibility for individuals. Adding that, section 613 of the MMA gives authority for additional test and frequency, not additional individuals.

Response: There is no statutory authority to expand eligibility for individuals. Section 613 of the MMA establishes coverage for beneficiaries who are at risk for developing diabetes. Beneficiaries who are pre-diabetic fall within 1861(yy)(2)(D) or (E) and are at an increased risk for developing diabetes. This increased risk separates them from the general at-risk population and requires the course of their care to be managed closer and more frequently.

For individuals not meeting the ''pre-diabetes'' criteria, we proposed that one diabetes screening test be covered per individual per year.

Comment: Several comments were received that recommended we provide physicians with clear guidance about Medicare's covered services to help patients control their diabetes. The commenters also asked that we inform providers about other covered services, such as Hgb1AC tests, that will help patients avoid painful diabetes-related complications.

Response: We will be releasing two publications. The *Dear Doctor Package* publication, which includes the ''2005 FACT SHEET'', will be sent to the contractors on a CD on or about October 15, 2005 and distributed to the providers by November 15, 2005. The *Medicare Coverage of Diabetes Services and Supplies* publication was originally written in 2002. It was revised in 2003 to update the Part B premium amount and is being revised again this year to update the premium amount and to include any information relevant to the MMA. This document will be available on the CMS Web site and at 1–800–MEDICARE.

Comment: We received several comments suggesting that screening should not require a physician's prescription or referral in order to be covered under Medicare Part B. This approach would follow the successful precedent established by us with other screening tests such as mammograms.

Response: The legislative history on mammography did result in us allowing self-referral for mammograms. However, Medicare rules have required that laboratory tests for screening or other diagnoses must be ordered by licensed health care practitioners, specifically physicians, PAs, NPs, or CNSs.

Comment: Comments were received recommending that the final rule include coverage of one annual diabetes screening for all Medicare beneficiaries.

Response: The benefit of screening all Medicare beneficiaries is not supported by current evidence. We plan risk-based frequency limitations of coverage for diabetes screening based upon the statute requirements. Furthermore, we believe beneficiaries with pre-diabetes may warrant a more frequent follow-up and this is permitted at the professional judgment of the health care practitioner.

Comment: We received a few comments suggesting the addition of the C-peptide test, as it is sometimes useful in Type 1 or Type 2 diabetes.

Response: We believe that C-peptide testing is appropriate for diagnostic evaluation, but not for screening. It is currently covered under the general lab benefit as a diagnostic test when it is medically necessary.

Comment: The American Society for Clinical Pathology (ASCP) has urged us to add CPT 82950 glucose; post glucose dose (includes glucose). This test is more frequently used to screen for diabetes. GTT is a more definitive test usually requested when questionable results from random, fasting or postprandial glucose levels are obtained. As written, the proposed rule appears to exclude 82950 as a screening test.

Response: We appreciate attention being drawn to the apparent exclusion of CPT code 82950, which was not our intention and we have corrected that omission.

Comment: A commenter suggested that due to increased incidence of obesity in recent years that family history of diabetes be defined as persons with Type 2 Diabetes in one or more first or second-degree relatives.

Response: The comments received did not provide a clear consensus on the definition of family history of diabetes. Thus the definition of family history of diabetes will be left to the professional judgment of the treating physician or qualified non-physician practitioner based on the beneficiary's medical history and best practice standards.

Comment: The American Clinical Laboratory Association (ACLA) believes that the other codes on the NCD routine screening list that currently result in a diabetes denial on the basis of routine screening should be covered under the new diabetes screening benefit.

Response: We believe the majority of individuals who will seek care under this benefit will conform to the V77.1 code. We are willing to review a sample of claims and determine if other specific codes are appropriate code for this benefit. Codes that need to be considered for this new benefit can be brought to our attention through the national coverage determination process for laboratories.

Comment: A comment was received recommending that the proposed rule be clarified to refer to a ''fasting blood glucose test'' rather than a ''fasting plasma glucose test'' since the CPT code

does not differentiate between blood and plasma.

Response: We agree with the recommendation to change the term ''fasting plasma glucose test'' to ''fasting blood glucose test''.

Comment: A comment was received recommending additional diabetes screening tests be added through a less formal process of consultation with manufacturers, health care providers, patients, and other stakeholders, as contemplated by Congress. The commenter further stated that the NCD process is complex and time consuming, delaying the coverage of new tests.

Response: We believe the evidence-based NCD process is an effective process to review and analyze items and services as potential benefits for Medicare beneficiaries. Because the NCD process allows for public comment before we make any changes, we believe this is the appropriate process for any future changes. Further, we may not be able to accept every stakeholder's recommendation because of instructional, coding, or claims issues which must be resolved before any benefit can be implemented.

Result of Evaluation of Comments

Our review of the comments has led to the elimination of the word ''plasma'' from the term ''fasting plasma glucose test.'' The word ''plasma'' will be replaced with the term ''blood''. We have corrected the unintentional omission of CPT code 82950, post glucose dose (includes glucose) as a diabetes screening test. The providers and beneficiaries are reassured that there will be clear guidance on covered services by way of two publications: The *Dear Doctor Package*, which includes the ''2005 Fact Sheet'' and *Medicare Coverage of Diabetes Services and Supplies*. We continue to promote healthcare practitioner autonomy with our policy of risk-based frequency limitations on items and services provided to our beneficiaries. We recognize the differing opinions with regard to the usage of the NCD process to review potential new items and services such as new diabetes screening tests for our beneficiaries. To provide transparency, timeliness and fairness, a formal process is necessary. Historically, the NCD process has been open to all interested parties and has proven to be an effective process.

Based on reasoning from the responses to the comments we received, at this time we will not be accepting the following suggestions.

- Reversing policy requiring a physician's or a qualified non-physician's prescription or referral for diabetes screening tests.
- Providing coverage of one annual diabetes screening test for all Medicare beneficiaries.
- Adding coverage of C-peptide test as a screening test.
- Bypassing the current NCD process for a less formal process to add additional diabetes screening tests.

C. Section 612—Cardiovascular Screening

Section 612 of the MMA adds section 1861(xx) to the Act and provides for Medicare coverage of cardiovascular (CV) screening blood tests for the early detection of CV disease or abnormalities associated with an elevated risk for that disease effective on or after January 1, 2005.

Upon reviewing the USPSTF reports, the scientific literature and comments of professional societies, trade associations, the industry, and the public, we proposed in the August 5, 2004 **Federal Register**, that the benefit for CV screening would include the use of three clinical laboratory tests to detect early risk for CV disease. Since the three tests, a total cholesterol, a HDL-cholesterol, and a triglycerides test, could be ordered as a lipid panel or individually, the frequency was limited to one of each individual test or combination as a panel every 5 years.

When we researched the benefit, some scientific experts proposed that the use of only the total cholesterol test as a single test every 2 years was adequate. After reviewing the literature and comments, we concluded that each test in the lipid panel is important since each test predicts the risk for CV disease independently. It would be prudent, therefore, to promote the benefit as three separate tests every 5 years. The decision to limit the frequency to 5 years, rather than more frequent testing every 2 years was due to information found in the Clinical Considerations of the USPSTF which indicate that the cholesterol values of elderly persons, who are the majority of the Medicare population, change slowly as they age. We also proposed that any changes to the list of tests could be made after a review of recommendations by the USPSTF and the use of the NCD process.

We proposed that for the claims processing and payment system, the coding of the tests would be made using the CPT codes available for the lipid panel or the three tests individually coded with the use of V codes to identify the tests were ordered for screening purposes. We also stated that we would pay for these CV screening tests at the same amounts paid for these tests to diagnose an individual with signs of CV disease and that these would be paid under the clinical laboratory fee schedule. The proposed coverage requirements were set forth in new § 410.17.

In response to the proposed rule, we received letters and e-mails from 28 commenters representing professional societies, trade groups, the industry, and individuals, who wrote on 26 different issues. One commenter represented 14 medical societies. Each commenter had many concerns and the comments were grouped into 26 areas of concern.

Comment: Three commenters expressed concern that many laboratories perform direct measurement LDL reflexively when triglycerides exceed certain parameters. The commenters are concerned that if screening direct measurement LDL is statutorily excluded then the Medicare beneficiaries would be liable for these tests without prior notice.

Response: Section 410.32 requires that tests be ordered by a treating physician and used in the management of the patient. We have interpreted this provision to restrict the furnishing of reflex testing to situations where it is clear that the physician is ordering reflex testing at specific parameters and where the physician has an option to order the test without the reflex portion. Thus, laboratories must offer physicians the ability to order a lipid panel without the option to perform the direct measurement LDL. We strongly encourage physicians to order lipid panels without the direct measurement LDL reflex option to protect Medicare beneficiaries from incurring a charge for this service without advanced notice.

If the screening lipid panel results indicate a triglyceride level that indicates the need for a direct measurement LDL, the physician may order this test once the results of screening lipid panel are reported. The NCD for lipid testing includes coverage of direct measurement LDL for patients with hyperglyceridemia. *[http://www.cms.hhs.gov/ mcd/viewncd.asp ?ncd_id=190.23&ncd_ version=1&show=all]*

We do not require the patient to physically return to the treating physician for an office visit and ordering of subsequent testing. Physicians may order such tests based on the results of the CV screening. The Medicare law and regulations do not prohibit the use of the same sample of blood to be used for direct measurement LDL following a lipid panel with very high triglycerides. Laboratories may archive the initial specimen and use it

for subsequently ordered medically necessary direct measurement LDL.

Comment: One commenter suggested that if the direct LDL cholesterol is included in the CV risk screening benefit, we must provide guidance to laboratories regarding whether or not the direct LDL must be billed with the −59 modifier for the charge to be reimbursed.

Response: Since the direct LDL cholesterol is not being added to the CV screening benefit, there is no change to the billing.

Comment: One commenter requested that the V codes (V81.0, V81.1, and V81.2) be added to the Lipid NCD and that the NCD Edit Software be modified to accept these V codes (V81.0, 81.1, and 81.2) on a frequency basis.

Response: The Laboratory NCD Edit Module will be modified to accept the V codes for matching the CPT codes with the ICD–9–CM code for those tests within the lipid NCD that are part of this statutory benefit. The entire lipid NCD is not open for modification. The frequency is determined by the NCD process and implemented through changes to the claims processing system to edit the patient history and coding.

Comment: One commenter asked that Medicare contractors provide explicit instructions to physicians to provide the necessary V codes (or their corresponding narratives) since screening is normally non-covered.

Response: We will release the appropriate manual, transmittal instructions and information from our educational components for the medical community including a MedLearn Matters article and fact sheets such as the ''2005 Payment Changes for Physicians and Other Providers: Key News From Medicare for 2005.'' Laboratories can join this effort to educate physicians and beneficiaries by distributing their own communication, bulletins or other publications. Some of this information will also be part of the ''Welcome to Medicare Preventive Services Package.''

Comment: Three commenters recommended that high sensitivity C-reactive protein (hsCRP) be considered as a test for this benefit since the AHA and CDC issued a Class IIa recommendation stating that hsCRP measurements for risk stratification add important information to the ''classic'' cholesterol and HDL measurement. They cited that given Congressional intent, we should include this measure in its list of ''approved'' screening tests and, if not, that we immediately request that USPSTF conduct a formal review of hsCRP as a screening test. Four commenters recommended the addition of the ABI test. Another requested the inclusion of the 12-lead ECG, the echocardiogram, and tests for carotid artery disease. Another requested the coverage of blood pressure screening. Finally, another commenter suggested that we allow the broadest access and maximize the potential for tests.

Response: We appreciate the commenters' suggestions to include hsCRP and the other tests. In our efforts to develop the proposed rule, many tests were considered for inclusion in the list of screening tests for this benefit. There was insufficient evidence to include any additional tests beyond the lipid panel tests. The information we received in the development of the proposed rule did not support the inclusion of these additional tests but we invite the public to submit scientific literature for our consideration. Other new types of CV screening blood tests may be added under this new screening benefit if we determine them appropriate through a subsequent NCD. 68 FR 55634 (Sept 26, 2003) or *http://www.cms.hhs.gov/coverage/8a.asp].*

Comment: Two commenters recommended that we add HCPCS codes for the Lipid Panel and components as waived tests since they are performed in physician offices and other sites with Clinical Laboratory Improvement Amendments (CLIA) Certificates of Waiver.

Responses: Under CLIA, a facility with a CLIA certificate of waiver can only perform those tests that are approved by the FDA as waived tests. We update the list of waived tests and their appropriate CPT codes on a quarterly basis through our program transmittal process. When we program the claims system to look for the AMA CPT codes for Lipid Panel or any of the three tests which make up the panel, the system will recognize those waived tests performed using the same code plus the QW modifier that are medically necessary.

Comment: Two commenters requested clarification of the frequency limits for the three tests considered for this benefit. They asked if we would cover: (1) A lipid panel; (2) one or more component tests making up the lipid panel once every 5 years; or (3) each of the 4 HCPCS codes listed every 5 years.

Response: The intent of the benefit is to screen for CV disease. Since we believe most physicians would order the Lipid Panel as a single test, our intention was to cover the panel. We recognize that physicians may have different approaches to reaching their decision to treat, and therefore, we have to make available the possibility that physicians could order the individual tests which make up the panel. No matter how the physician(s) order the tests, our intention is to cover each of the 3 component tests (that is, a total cholesterol, a triglycerides test, and an HDL cholesterol) once every 5 years.

Comment: Two commenters asked that we clarify the reasons for having V codes for screening tests added from the MMA rather than the past practice of developing G codes (unique HCPCS codes; temporary codes). This commenter believed that the change to V codes would cause confusion to the databases like the Physician/Supplier Procedure Summary Master File. This confusion would result in improperly filed provider claims and this would lead to a different and confusing method of processing claims.

Response: The decision to use ICD–9–CM codes rather than continue to add G codes was made because we try to utilize existing coding structures where possible and create G codes if there is a specific programmatic need. The laboratory community has lobbied against the use of G codes for a few years. Also the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Standardization Requirements are working toward phasing out G codes, which are CMS only codes. The claims processing and editing systems are expected to be adjusted to manage this change.

Comment: Five commenters questioned the reasons for establishing limits on the frequency of this benefit since this places great legal, administrative, and financial burden for providers to manage this type of information. One commenter suggested the use of a chit that beneficiaries would receive and redeem for testing so laboratories would not need to keep records.

Response: The statute requires a frequency limit. Since laboratories may not have the complete medical history for individuals, including their history of CV screening tests, they are largely relying on the physician's order in establishing whether the test is medically necessary and covered by Medicare. However, relying on the physician's order does not provide the laboratory with proof that the CV screening test is medically necessary since the beneficiary may be treated by multiple physicians who may have ordered these tests independently within the 5 year coverage window. If the laboratory has sufficient doubt, the laboratory may issue an Advanced Beneficiary Notice (ABN) to the beneficiary indicating that Medicare may not cover the CV screening test. If the laboratory does not issue an ABN to

the beneficiary who has received more that one CV screening test during the previous five years, the laboratory may be financially liable for the cost of the test. Laboratories are not required to issue an ABN if the physician has already issued one.

In addition, section 40.3.6.4(C) titled ''Frequency Limited Items and Services'' of Chapter 30 of Pub 100–4 of the ''Internet Only Manual'' provides additional guidance for those instances where Medicare has imposed frequency limitations on items or services. This section instructs providers that the provider may routinely give ABNs to beneficiaries and that whenever such a routine ABN is provided to a beneficiary, the ABN must include the frequency limitation as the reason for which Medicare will deny coverage.

Comment: Several commenters, including the ACR and the SIR, offered their assistance to us when we determine whether noninvasive testing for CV disease is necessary.

Response: Since the organizations that suggested noninvasive tests for inclusion in this benefit provided the materials for our review, it is not necessary for us to seek outside assistance. We appreciate the commenters' offer of assistance.

Comment: Four commenters suggested that the CV screening benefit stipulate an age for the population to be tested. We reviewed the USPSTF recommendation that promoted testing for men 35 years and older and women 45 years and older. The commenters believe this age range should be lowered to include those aged 20 years and older and asked us to consider including younger people in this benefit.

Response: The statutory change for this benefit did not include an age for the person to be tested. While some of the USPSTF recommendations included an age or an age range, none was selected for the proposed rule. Since the majority of the individuals in Medicare are generally 65 and older, the belief was that we are looking at an older population rather than concentrating our resources on the younger beneficiaries who may also be disabled and Medicaid eligible or could be eligible for other services due to other complications of CV disease. While there may be individuals younger than 65 years of age that could benefit from this testing, this benefit is intended for those entitled to Medicare. Therefore, any patient entitled to Medicare would be covered for this benefit as specified in this rule.

Comment: One commenter noted that if the patient did not fast for the screening test (fasting may be difficult for some patients), the calculation of LDL cholesterol may be inaccurate. This commenter recommended that for screening purposes, an alternative to repeating the full lipoprotein profile in the fasting state would be a follow-up direct measurement of LDL cholesterol.

Response: If a patient cannot fast and the physician believes the patient's medical history and circumstances suggest the beneficiary is at risk of CV disease, then any additional testing beyond an initial screening would need to be done under the diagnostic clinical laboratory benefit. Under the screening benefit, a repeated full lipoprotein profile (fasting) or a second LDL cholesterol (fasting) would not be covered for anyone who failed to fast when they had their first set of tests.

Comment: Several commenters suggested that the tests that the USPSTF approves for CV screening blood tests be automatically adopted and covered by Medicare for the purposes of this benefit. We would not need to use the NCD process to add tests to this benefit. Immediate adoption of USPSTF recommendations will remove us from our own lengthy review.

Response: While the USPSTF process is well established, we believe it is prudent to review any recommendations from the USPSTF before implementing them. In the proposed rule, we asked the public how we should make changes for this benefit. Because the national coverage determination process allows for public comment before we make any changes, we believe this is the most appropriate basis for any future changes. Further, we may not be able to accept every USPSTF recommendation because of instructional, coding or claims issues that must be resolved before any benefit can be implemented.

Comment: Several commenters questioned whether the screening benefit for CV disease included noninvasive tests or whether it was limited only to blood tests. Further, they recommended that the adoption of noninvasive tests be tied to recommendations of the USPSTF or to an NCD.

Response: We interpreted this portion of the screening benefit to permit noninvasive tests for which there was a blood test recommended by the USPSTF (for example, there is a blood test for cholesterol and if a noninvasive test was developed that detected characteristics of cholesterol, could provide a meaningful (comparison) result and accurate reading) then the noninvasive test could be considered for inclusion in the screening benefit. Noninvasive tests would not be immediately included but would be subject to a review before adoption. When it is time to consider the addition of tests or changes to the list of tests, we will consider any changes through an NCD. This benefit is not limited only to blood tests.

Comment: One commenter recommended that we include a fasting blood glucose test as part of the CV screening blood benefit and that we cover this test every 2 years for beneficiaries over 45 and for younger beneficiaries who are obese or have a family history of diabetes. Fasting blood glucose is inherently a CV screening test because diabetes carries increased risk of CV disease.

Response: While some people who have diabetes exhibit other factors associated with CV disease, we do not see the necessity to adjust the CV screening benefit to include a fasting blood glucose test. The diabetes screening benefit should be able to identify these individuals. Medicare does not plan to duplicate tests when they are available through other screening programs.

Comment: One commenter requested the inclusion of V70.0 for routine examination to be added as one of the ICD–9-CM codes to be covered for screening for CV screening blood tests. They asked that the NCD on lipid panel be reviewed for any codes that were previously denied as routine screening in the past, and that these codes be considered for inclusion under this new benefit.

Response: We believe the majority of individuals who will seek care under this benefit will fit the V81.0, V81.1, or V 81.2 codes. We are willing to review a sample of claims and determine if V70.0 is an appropriate code for this benefit. At this time, we are unable to add V70.0 to the instructions being cleared. Codes that are to be considered for this new benefit must be brought to our attention through the national coverage determination process for laboratories.

Comment: One commenter suggested that the proposed § 410.17 include reference to whether beneficiaries will incur out-of-pocket costs for CV screening blood tests.

Response: Section § 410.17 is specific to coverage instructions for screening tests for the early detection of CV disease. We do not believe it is necessary to revise § 410.17 to include payment instructions. We have indicated that Medicare would pay for the tests under the clinical laboratory fee schedule. Currently under this payment system, beneficiaries do not incur copayments and deductibles in accordance with section 1833(a)(1)(D)(i) of the Act, and is included in

instructions at Medicare Claims Processing Manual, Pub. 100–04, chapter 16, § 30.2.

Comment: Two commenters asked us to clarify why we chose 5 years as the timeframe for the benefit, rather than the 2 years allowed by the statute.

Response: Our primary goal was to allow testing for the population that needed to be screened. In the preamble to the proposed rule, we stipulated that the Clinical Considerations of the USPSTF indicate, while screening may be appropriate in older people, repeated screening is less important because lipid levels are less likely to increase after age 65. Screening individuals more often than necessary might lead to unnecessary expenses and treatment. The scientific literature indicates that lipid levels in the elderly are fairly stable. Therefore, we proposed screening once every 5 years and have not received sufficient evidence to change this position.

Comment: Two commenters suggested that a two-tiered benefit be developed that would allow lipid profile screening tests at least every 5 years for beneficiaries when risk factors are not evident and a second group be screened at least every 2 years. The second group would include individuals who have modifiable risk factors (for example, tobacco smoking, high blood pressure, physical inactivity, obesity, and diabetes mellitus) and non-modifiable risk factors (such as age, gender, race, and family history).

Response: While the CV screening benefit could be expanded to include individuals other than those mentioned in the proposed rule, preventive benefits were added to the Medicare Program on a limited basis as science and technology permit them. Since some of the individuals in the second group already would be screened through the IPPE and the Diabetes Screening Benefit, we are not developing a second tier at this time. We believe expanding this to a second tier would waste precious resources of time and money and not contribute to lowering the risk factors for individuals with CV disease.

Comment: One commenter questioned why we proposed to use the NCD process as the method of making changes to the list of tests covered by the CV screening blood test benefit. The commenter wrote that the MMA does not require that the NCD process be utilized. They indicated that there is no need for us to conduct our own assessment since a thorough evaluation of the test was to be done by the USPSTF in determining that the test is one that it recommends. The commenter objected to the use of the NCD process for consideration of new tests because of the significant delays that mark this process. The commenter also stated that all that would be needed for us to approve the coverage of additional CV screening tests is the recommendation of the USPSTF.

Response: In establishing the benefit for CV screening blood tests, the Congress gave the Secretary the authority to determine which tests would be covered by this benefit. We do not believe it would be proper to delegate this function to USPSTF or any other entity. In the proposed rule, we proposed the tests to be covered for the new benefit when it becomes effective January 1, 2005 and at the same time, we offered the NCD process for changes to this benefit. We proposed that future tests would be added after reviewing the recommendations of the USPSTF and the use of the NCD process. The NCD process actually has several methods for evaluating which tests we may eventually cover. The NCD process includes an application for a new coverage issue, a reconsideration of an existing policy, or a coding change for laboratory tests. We believe the use of the NCD process is a worthwhile endeavor since it is a public process and less time consuming than rulemaking. The use of an NCD is authorized by Section 1871 of the Act.

Comment: One commenter suggested that we include triglycerides as a test for the CV screening blood test benefit since the 2001 USPSTF recommendations for screening for lipid disorders associated with CV disease only includes measurement of total cholesterol and high-density lipoprotein cholesterol (HDL–C).

Response: We have included the triglycerides test as one of the tests for screening for CV disease. For some individuals, triglycerides may detect a risk factor for CV disease. That is why it was more prudent to select a lipid profile that includes the three tests (total cholesterol, HDL-C, and the triglycerides) rather than to indicate the use of individual tests with different test intervals and different ordering patterns.

Comment: One commenter requested that the frequency limit for lipid testing of 5 years be waived if the patient develops a risk factor, such as diabetes, a marked weight gain, etc. in the interval.

Response: A patient screened for lipid testing could also meet the requirements for screening under the diabetes screening benefit. If a patient developed further risk factors which negate the need for continued screening under the CV screening blood test benefit, their additional signs or symptoms would probably cause the person to need to seek treatment which would be covered under other benefits including diagnostic clinical laboratory testing.

Comment: One commenter questioned whether § 410.16 that permits qualified nurse practitioners and others to order CV screening tests under the physical examination (section 611 of the MMA) is inconsistent with § 410.17 that requires that the laboratory tests be ordered by the treating physician (§ 410.32(a)).

Response: Section 410.16 addresses services by NPs because of conforming changes made in section 611(d) of the MMA. Section 410.32(a)(3) permits certain NPPs to furnish services that would be physicians' services if furnished by a physician and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit. We believe that the statute permits the use of NPPs to order tests described under § 410.17 without a change in the statute. The general rule for laboratory tests is that the tests must be ordered by the treating physician and in the instance of screening tests, the treating NPP may be regarded as a physician for this purpose.

Comment: One commenter believed that screening every 5 years was too long a period between tests and that the data we collect be used to allow more frequent testing.

Response: We have heard from commenters that the frequency limitation of keeping records for the 5 years is difficult because of storage, access and retrieval, and orders from multiple physicians. Change in the frequency (that is, the number of times a patient can be tested during a given timeframe) will be considered if the scientific literature supports it. We do not believe we are permitted to change the frequency based solely upon the logistical difficulties in collecting, consolidating, and maintaining administrative data. Modifying the benefit to permit more frequent testing will not resolve these administrative difficulties. However, we will take this recommendation under advisement as we continue to consider the associated clinical data, but will not make any changes for the final rule.

Comment: One commenter requested that blood be removed from the title of this benefit for the final rule. The commenter believed the narrow focus on blood would restrict the types of tests that would be administered for detecting CV disease.

Response: In developing the proposed rule, we included blood in the title of this benefit to be consistent with the

history of this benefit and to distinguish the tests in the benefit. We believe that noninvasive tests could be covered and this benefit is not limited only to blood tests.

Comment: One commenter suggested that the CV screening benefit include an appropriate screening instrument. As with depression, the examining physician has a test based on clinical practice guidelines to use as a tool for assessing the patient. Since the American Heart Association (AHA) and the ACC Guidelines for PAD are expected to be published in 2005, the commenter is requesting that we adapt the patient assessment and include these guidelines under the CV screening benefit.

Response: Since the publication of the AHA and ACC Guidelines has not taken place, it would be difficult to evaluate this document and how physicians would use this in the course of examining a patient. Physicians may use their best judgment for how they assess an individual patient and whether additional specific tests from the AHA and ACC guidelines would be more helpful than what is already included in the screening benefit for CV disease is not something we can conclude at this time. The NCD process is available when additional tests should be considered.

Result of Evaluation of Comments

After reviewing all the comments, we have plans to include the V codes (V81.0, V81.1 and V81.2) in the Laboratory Edit Module, and to release manual and transmittal instructions and information to smooth the transition for the new benefit. Providers who routinely give ABNs to beneficiaries must include in the ABN that the frequency limitation is the reason for which Medicare will deny coverage. A patient who has an ABN and exceeds the frequency limitation may incur out-of-pocket charges. We will finalize the changes to § 410.17 as proposed.

D. Section 413—Physician Scarcity Areas and Health Professional Shortage Areas Incentive Payments

[If you choose to comment on issues in this section, please include the caption ''HPSA Zip Code Areas'' at the beginning of your comments.]

Section 413(a) of the MMA provides a new 5 percent incentive payment to physicians furnishing services in physician scarcity areas (PSAs). The MMA added a new section 1833(u) of the Act that provides for paying primary care physicians furnishing services in a primary care scarcity county and specialty physicians furnishing services in a specialist care scarcity county an additional amount equal to 5 percent of the amount paid for these services.

Section 1833(u) of the Act defines the two measures of physician scarcity as follows:

1. Primary care scarcity areas—determined by the ratio of primary care physicians to Medicare beneficiaries. A primary care physician is a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist.

2. Specialist care scarcity areas—determined by the ratio of specialty care physicians to Medicare beneficiaries. The specialist care PSA ratio includes all physicians other than primary care physicians as defined in the definition of primary care scarcity areas.

To identify eligible primary care and specialist care scarcity areas, we ranked each county by its ratio of physicians to Medicare beneficiaries. In accordance with the statute, in the list of primary care and specialist care scarcity counties, only those counties with the lowest ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties were considered eligible for the 5 percent incentive payment. In accordance with the section 1833(u) of the Act, we also treated a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification) as an equivalent area (that is, equal to a full county).

Consistent with section 1833(u)(4)(C) of the Act, all PSAs were assigned their 5-digit zip code area so that we may automatically provide the 5 percent incentive payment to eligible physicians. For zip codes that cross county boundaries, we used the dominant county of the postal zip code (as determined by the U.S. Postal Service) to identify areas eligible to receive the 5 percent payment. Section 1833(u)(4)(C) of the Act also requires us to publish a list of eligible areas as part of the proposed and final physician fee schedule rules for the years for which PSAs are identified or revised and to post a list of PSAs on our Web site. *See* Addenda J and H for the zip codes of primary care and specialist care PSAs. The PSA lists by zip code and county are also available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment.* Since we are publishing these lists for the first time in this final rule with comment period, we are accepting comments for 60 days after the date of publication of this regulation on the zip codes and counties qualifying as physician scarcity areas and will address the comments in next year's fee schedule.

In addition to creating of the 5 percent PSA incentive payment, section 413 of the MMA amended section 1833(m) of the Act to mandate that we pay the 10 percent health professional shortage areas (HPSA) incentive payment to eligible physicians in full county HPSAs without any requirement that the physician identify the HPSA area. We can only achieve this result by assigning zip codes to eligible areas. *See* Addenda I and K for the lists of eligible primary care and mental health HPSAs by zip code. Consistent with the Act, we have also posted a list of links on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment* to assist those physicians located in eligible areas where automation is not feasible, that is, the eligible area could not be assigned a zip code.

In the August 5, 2004 proposed rule, we proposed conforming changes to our regulations to add § 414.66 to provide a 5 percent incentive payment to eligible physicians furnishing covered services in eligible PSAs. We also proposed conforming changes to our regulations to add § 414.67 to codify the 10 percent incentive payment to eligible physicians furnishing covered services in eligible HPSAs, established under the Omnibus Budget Reconciliation Act of 1987 (OBRA) (Pub. L. 100–203), previously implemented through manual issuance.

We received 23 letter comments on the bonus payment provisions of section 413 of the MMA. A summary of those comments and our responses follows:

Comment: One commenter questioned the rationale behind using zip codes for the purpose of identifying eligible areas for physician bonuses. The commenter believes that zip codes are less accurate than political boundaries (counties, census civil divisions, and census tracts).

Response: The statute requires the identification of PSAs on a county basis, except for rural areas (using the Goldsmith Modification). At this time, we can only determine physician scarcity for Goldsmith areas at the zip code level since the Medicare beneficiary data is currently unavailable at the census tract level.

Automation of physician bonus payments can only be achieved by assigning zip codes to eligible areas. That is, the zip code place of service is the only data element reported on the Medicare claim form that would allow automation.

Comment: A commenter believes that our proposal to identify qualified PSAs and HPSAs by zip code for automatic payment purposes is problematic

because zip codes cross county lines. The commenter suggested that a more user-friendly option would be to add a county identifier to the claim form.

Response: The addition of a county code would not resolve the issue of identifying the claims that would have a bonus because not all designated HPSAs and PSAs are full counties. We cannot identify, for an automated payment, services furnished in counties that are only partially designated and Goldsmith areas that are not full counties. In addition, there currently is no place on the standard electronic claims form to accommodate the entry of a county code.

Comment: A commenter requested clarification regarding circumstances when automation of bonus payments is not feasible.

Response: When the boundaries of zip code areas precisely overlay with the boundaries of eligible HPSAs and PSAs, automation of bonus payments is feasible. In other words, eligible physicians furnishing services to Medicare patients within these zip code areas will automatically receive their bonus payments. We can also automate bonus payments within zip code areas that cross outside of qualified county boundaries as long as the zip code, as determined by the U.S. Postal Service, is dominant to the qualified scarcity county. We cannot automate bonus payments when boundaries of zip code areas only partially coincide with the boundaries of HPSAs and PSAs.

Comment: One commenter requested clarification regarding the application of the billing modifier in determining physician eligibility. The commenter inferred from the proposed rule that, if the zip code is not posted as a qualified area, an eligible physician could still receive a bonus payment if a modifier is used.

Response: Eligible physicians furnishing covered services in a portion of an eligible PSA, which cannot be properly assigned a zip code to permit automation of the bonus payment, would need to include the new physician scarcity modifier on the Medicare claim in order to receive the bonus payment. Lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus are available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment.* If a service is provided in a zip code area that is not listed on the automated payment files, but is within a designated physician scarcity county, the physician must submit the ''AR'' billing modifier with the service in order to receive the bonus payment. Separate lists for the primary care PSAs and the specialty care PSAs are provided on our Web site for both the automated zip codes and the counties.

Comment: A commenter requested clarification on what ratios would be used to identify PSAs. The Health Resources and Services Administration (HRSA) uses a national ratio of 3,500:1, or 3,000:1 if high needs are shown. The commenter requested information on which ratios would be used to determine PSAs for specialty providers, and whether the ratios would be different for different specialty care providers.

Response: Only those counties with the lowest primary care ratios that represent 20 percent of the total number of Medicare beneficiaries residing in the counties will be considered eligible for the 5 percent incentive payment. In other words, we ranked each county by its ratio of physicians to beneficiaries and then designated counties as scarcity areas with the lowest ratios until 20 percent of the Medicare population was reached. A separate specialist physician ratio was calculated to identify specialist care PSAs using the same methods stated. The statutory mandate precludes us from adopting a national physician-to-patient ratio similar to the HPSA designations. By statute, the 20 percent population threshold must serve as the qualifying condition for all counties/rural areas.

For calculating the ratios, section 1833(u)(6) of the Act, as added by the MMA, defines a primary care physician as a general practitioner, family practice practitioner, general internist, obstetrician, or gynecologist. In accordance with the statute, all other physicians were grouped together as specialists for purposes of determining the specialist care PSA list.

Comment: A commenter requested clarification regarding the frequency of updating the eligible zip code list for automatic HPSA bonus payments and its impact on otherwise eligible physicians.

Response: Determination of zip codes eligible for automatic HPSA bonus payment will be made on an annual basis, and there will not be any mid-year updates. We will effectuate revisions made to designations by HRSA the following year for purposes of automatic bonus payments. Consequently, if HRSA changes to the HPSA designations remove physicians in those areas from receiving automatic payment, the zip code areas will remain eligible until the next year when we remove the zip code from our approved list.

Eligible physicians furnishing covered services in newly-designated HPSAs are permitted to add a modifier to their Medicare claims to collect the HPSA incentive payment until our next annual posting of eligible zip codes for automation of bonus payments. In cases where a zip code cannot be properly assigned to the newly-qualified HPSA, physicians furnishing services in the area must continue to bill for the incentive payments using the appropriate modifier.

Comment: A commenter requested that we provide FQHCs with the 5 percent PSA incentive payment. Since the statute does not explicitly exclude other physicians' services (that are billed on an all-inclusive basis), such as those provided in FQHCs or RHCs, the commenter stated that we should extend the new 5 percent bonus payment to FQHC physicians.

Response: As defined in section 1861(aa) of the Act, FQHC and RHC services are not physicians' services, even though physicians' services are frequently a component of the services furnished in these facilities. The services are rather identified as FQHC services. Therefore, services furnished by these providers are not eligible for the incentive payment.

Comment: A commenter has questioned our proposal not to apply the new 5 percent physician incentive payment to the technical component of physicians' services. The commenter stated that extending the new bonus payment to both the professional and technical component of the physicians' services is consistent with Congressional intent and would simplify claims processing.

Response: Section 1833(u) of the Act provides for incentive payments for physicians' services furnished in PSAs. We note that the statute contains two definitions of physicians' services. The first, which appears at section 1861(q) of the Act, defines physicians' services as ''professional services performed by physicians including surgery, consultation, and home, office, and institutional calls.'' The second, which refers to services paid under the physician fee schedule, is found at section 1848(j)(3) of the Act and contains a broader definition of physician services. However, that definition applies only for purposes of section 1848 of the Act.

Since the incentive payment is not included in section 1848 of the Act, the definition of physicians' services specified in section 1861(q) of the Act is the definition that applies. Thus, we believe the best reading of the statute is that only *professional* services furnished

by physicians are eligible for incentive payments.

Comment: A commenter recommended that we extend the HPSA bonus payment to all physicians, regardless of their specialty, when their services are furnished within a mental health HPSA. The commenter believes there is no statutory basis to limit incentive payments just to psychiatrists within mental health HPSAs.

Response: We provide HPSA bonus payments in primary medical care HPSAs to all physicians regardless of specialty (including psychiatrists) in light of the fact that there is significant overlap between primary medical care HPSAs and mental health HPSAs. Furthermore, most primary medical HPSAs, especially in rural areas, also have shortages of specialists. Consequently, there is no apparent need to distinguish between physician specialties within primary medical care HPSAs for determining physician eligibility for bonus payment purposes. However, in the situation where the mental health HPSA does not overlap with a primary medical care HPSA, we allow only psychiatrists to collect the incentive payment. Within these stand-alone mental health HPSAs, there is an adequate supply of physicians for the provision of medical services and a shortage only of those providing mental health services. Therefore, it would be inconsistent with the HPSA incentive payment provisions, as well as an inappropriate use of the Medicare Trust Fund, to pay bonuses to physicians who furnish medical services in service areas without shortages of primary medical services.

Comment: A commenter requested that we count only those practicing physicians who treat Medicare patients when determining the ratio of beneficiaries to practicing physicians. To count all practicing physicians, including those who do not treat Medicare patients would undermine the intent of the provision.

Response: The statute does not permit us to count only Medicare participating physicians to determine PSAs. The statute explicitly requires that we calculate the primary and specialist care ratio by the number of physicians in the active practice of medicine or osteopathy within the county or rural area. Therefore, we must include in the physician tally all actively practicing physicians when determining PSAs.

Comment: A commenter asked that we clarify our methods for determining the number of primary care and specialty care physicians to calculate the physician-to-beneficiary ratio for identifying PSAs. The commenter suggested that we use only the number of practicing physicians when determining the beneficiary to physician ratio, that is, distinguish between licensed physicians and practicing physicians when determining ratios of primary care and specialty care since some physicians continue to be licensed after they retire.

Response: As required by section 413 of the MMA, the determination of eligible PSAs is based on the ratio of ''active practice'' physicians to Medicare beneficiaries within a county or rural area (using the Goldsmith Modification). The physician data source used in calculating scarcity areas is contained in the following:

- The 2001 Physician Characteristics file; and
- The 2001 Physician Address file.

These data are a compilation of:

- The December 2001 AMA Master file;
- The December 2001 American Osteopathic Association (AOA) Physician file; and
- The National Health Service Corps 2001 participant listing.

These physician data files allow for the identification of the physician's active status. Some of the key status indicators to identify practicing physicians include ''clinically active'' and ''Federal employment'' status. Clinically active status was determined using the type of practice, professional employment, and major professional activity fields from AMA and AOA. For example, determining non-active status is based on physicians who—

(1) Are involved in administration, medical teaching, research, and other non-patient care activities; or

(2) Have self-identified as fully retired or otherwise inactive.

We believe that the indicator field of ''fully retired or otherwise inactive'' addresses the specific issue of a physician maintaining his or her license after he or she retires.

Comment: A commenter expressed concern about our use of the AMA database to determine the number of licensed physicians engaged in direct patient care in each State. The commenter claims that the AMA database overstates the number of practicing physicians in the State of California by at least 10,000 physicians. In light of this concern, the commenter stated that we should use State medical board licensing information rather than the AMA database in determining the physician counts.

Response: The physician data source used in calculating scarcity areas is contained in the 2001 Physician Characteristics file and the 2001 Physician Address file. These data are a compilation of the December 2001 AMA Master file, the December 2001 AOA Physician file, and the National Health Service Corps 2001 participant listing. We made the decision to use the AMA Master file as well as the other files as the sources of physician data in scarcity calculations because there is no other adequate source of national physician data. It may be possible to obtain physician data from each individual State agency, but doing so would entail considerable administrative and technical difficulties. Furthermore, methods of gathering and compiling data may be inconsistent in different States. State agencies may vary greatly in terms of the methods used to update physician databases, the frequency of updates, how the data are stored, the type of information collected, and so forth. In addition, States may use their own classification systems for physician specialties, types of practice, and other key information, and these systems may change over time.

Comment: A commenter encouraged us to implement similar incentive payment programs for non-physician practitioners, for example, Certified Registered Nurse Anesthetists and physician assistants.

Response: We do not have the authority to provide bonus payments to non-physicians. Sections 1833(m) and 1833(u) of the Act authorize bonus payments only to physicians.

Comment: A commenter requested that we immediately publish the already identified PSAs by zip code and specify the specialties in short demand within each eligible PSA.

Response: Lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus, are now available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment.* See Addenda J and H for the zip code list of PSAs for primary care and specialist care.

We have forwarded to the Health Resources and Services Administration the request for identification of specialties in short supply within PSAs. That Agency has responsibility for physician manpower issues.

Comment: A commenter requested that the list of scarcity areas should be made interim in the final fee schedule rule in order to give physicians sufficient time to review and comment on the proposal.

Response: Although we made these lists public on our Web site on October 1, 2004, we will accept comments for 60 days after the date of publication of this regulation on the zip codes and counties

qualifying as physician scarcity areas and will address the comments in next year's fee schedule.

Comment: A commenter expressed appreciation for our effort to fairly implement the incentive payments to physicians in scarcity areas. As this new incentive payment program is implemented, physicians must be informed that this bonus is available, and it must be simple for them to receive the bonus.

Response: We have already made available on our Web site at *http://www.cms.hhs.gov/providers/bonuspayment* the lists of the zip codes that are eligible for the automated payment, as well as a list of the counties that are eligible to receive the PSA bonus. We have also issued a *Medlearn* article to educate the physician community regarding Medicare physician incentive payment programs. For a copy of this provider education article go to: *http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SE0449.pd.* Lastly, Medicare's contractors have established their own Web site links for the HPSA incentive payment program to facilitate the payment of these bonuses to eligible physicians.

Comment: A commenter expressed support of our proposed changes relating to incentive payments for services provided in areas designated as HPSAs and PSAs. The commenter also commended us for our prompt implementation of section 413 of the MMA. Another commenter expressed appreciation that the new 5 percent incentive is available to specialists in counties with short supply of these physicians.

Response: We appreciate this positive feedback from the provider community.

Comment: A commenter has questioned the rationale for our policy of imposing, as a condition of eligibility, the requirement that the specific location at which the service is furnished must be considered a HPSA or PSA. Since physicians do not always reside in the county where they provide services, identifying PSAs on one basis and paying for them on another basis may be problematic.

Response: According to section 1833 of the Act, we make bonus payments for physicians' services furnished in an eligible HPSA or PSA. Thus, the place of service controls the availability of the bonus. A physician providing a service in his or her office, a patient's home, or in a hospital may receive the incentive payment only if the service occurs within an eligible shortage or scarcity area.

Comment: One commenter believes that podiatric physicians, who are considered specialists, should be among those eligible to receive the additional 5 percent incentive payment.

Response: Section 1833(u) of the Act, as added by the MMA, specifically defines ''physician'' as one described in section 1861(r)(1) of the Act. Therefore, we do not have authority to make bonus payments to podiatrists.

Commenter: A commenter expressed concern that our systems had trouble implementing the HPSA bonuses under Method II for Critical Access Hospital (CAH) participation, and some providers have waited more than two years for increased Medicare payments.

Response: Although some fiscal intermediaries may not have been accustomed to processing physician claims, these systems were updated and the problems resolved as of July 1, 2004.

Comment: A commenter from California requested that physicians who provide Medicare services only through managed care not be included in our calculations. The commenter believes that including physicians who only treat managed care patients in the count to determine physician scarcity areas will lead to a gross overstatement of the number of physicians available to provide care to fee-for-service Medicare patients.

Response: We do not believe that we have the legal authority to exclude managed care physicians from the ratio calculations. Moreover, excluding managed care physicians in the county-wide physician tally would not change PSAs in California based on our calculations. In fact, excluding the managed care physicians would make five eligible areas ineligible.

Result of Evaluation of Comments

We are finalizing § 414.66 and § 414.67 as proposed. We are accepting public comments on the zip code areas.

E. Section 303—Payment for Covered Outpatient Drugs and Biologicals

1. Average Sales Price (ASP) Payment Methodology

a. Background

Medicare Part B covers a limited number of prescription drugs and biologicals. For the purposes of this proposed rule, the term ''drugs'' will hereafter refer to both drugs and biologicals. Medicare Part B covered drugs generally fall into the following three categories:

- Drugs furnished incident to a physician's service.
- Durable medical equipment (DME) drugs.
- Drugs specifically covered by statute (for example, immunosuppressive drugs).

Section 303(c) of the MMA revises the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303(c) of the MMA amends Title XVIII of the Act by adding section 1847A, which establishes a new ASP drug payment system. In 2005, almost all Medicare Part B drugs not paid on a cost or prospective payment basis will be paid under this system.

The new ASP drug payment system is based on data submitted to us quarterly by manufacturers. Payment amounts will be updated quarterly based on the manufacturer's ASP calculated for the most recent calendar quarter for which data are available. We intend to implement the quarterly pricing changes through program instructions or otherwise, as permitted under Section 1847A(c)(5)(C). For calendar quarters beginning on or after January 1, 2004, the statute requires manufacturers to report their ASP data to us for almost all Medicare Part B drugs not paid on a cost or prospective payment basis. Manufacturers' submissions are due to us not later than 30 days after the last day of each calendar quarter.

The methodology for developing Medicare drug payment allowances based on the manufacturer's submitted ASP data is described in this final rule and reflected in final revisions to the regulations at § 405.517 and new Subpart K in part 414. Several comments discussed aspects of the manufacturers' calculation of ASP that are beyond the scope of this final rule. We did not propose any changes to the regulations concerning the manufacturer's calculation of ASP. We also received other comments regarding the use of the least costly alternative (LCA) methodology when pricing drugs, and requests for new HCPCS codes for drugs and coverage of compounded drugs. These comments are also outside the scope of this final rule. We did not propose any changes to the LCA policy, the HCPCS process, or coverage of compounded drugs.

b. Provisions of the Final Rule

i. The ASP Methodology

Effective 2005, payment for certain drugs and biologicals not paid on a cost or prospective payment basis furnished on or after January 1, 2005 will be based on an ASP methodology.

As described in section 1847A(b)(3)(A) of the Act for multiple source drugs and section 1847A(b)(4)(A) for single source drugs, the ASP for all

drug products included within the same billing and payment code [or HCPCS code] is the volume-weighted average of the manufacturers' average sales prices reported to us across all the NDCs assigned to the HCPCS code. Specifically, section 1847A(b)(3)(A) of the Act and section 1847A(b)(4)(A) of the Act require that this amount be determined by—

- Computing the sum of the products (for each National Drug Code assigned to those drug products) of the manufacturer's average sales price and the total number of units sold; and
- Dividing that sum by the sum of the total number of units sold for all NDCs assigned to those drug products.

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment allowance for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the HCPCS code. This payment allowance is subject to applicable deductible and coinsurance. The payment limit is also subject to the two limitations described below in section III.E.1.b.v of this preamble concerning widely available market prices and average manufacturer prices in the Medicaid drug rebate program. As described in section 1847A(e) of the Act, the payment limit may also be adjusted in response to a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and a concomitant increase in the price of the drug which is not reflected in the manufacturer's average sales price.

Section 1847A(b)(1)(B) of the Act requires that the Medicare payment allowance for a single source drug HCPCS code be equal to the lesser of 106 percent of the average sales price for the HCPCS code or 106 percent of the wholesale acquisition cost of the HCPCS code. This payment allowance is subject to applicable deductible and coinsurance. The payment limit is also subject to the two limitations described below in section III.E.1.b.v concerning widely available market prices and average manufacturer prices in the Medicaid drug rebate program. As described in section 1847A(e) of the Act, the payment limit may also be adjusted in response to a public health emergency under section 319 of the Public Health Service Act.

Comment: One commenter suggested that we implement the ASP methodology on a pilot basis prior to a national rollout. A physician interest group recommended that we delay the implementation of the ASP payment system for at least one year. The interest group stated that we should inform physicians of the ASP for all covered drugs before the final rule is issued and allow physicians to comment on the proposed rates after an informed and complete review process.

Response: The law requires that the new ASP-based drug pricing system be implemented January 1, 2005. The January 1, 2005 prices will be based on the data submitted to us no later than 30 days after the end of the third calendar year quarter of 2004. Given the requirements surrounding the timing of the promulgation of the physician fee schedule final rule, we will not have the January 1, 2005 prices available before the publication of the final rule. However, our goal is to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the January 1, 2005 effective date of those rates.

Comment: A provider asked that we earmark funds to enable physicians to transition from the AWP–15 percent payment system to the ASP + 6 percent payment system.

Response: We do not have statutory authority to create such a transition fund.

Comment: One commenter stated that the ASP plan does not account for price increases in a timely manner. Another commenter expressed concern that because ASP modifications lag by at least two calendar quarters, market prices would not be reflected in a drug's payment limit for at least six months after a pricing adjustment.

Response: The ASP methodology is based on average sales prices reported by manufacturers quarterly. Manufacturers must report to us no later than 30 days after the close of the quarter. We implement these new prices through program instructions or otherwise at the first opportunity after we receive the data, which is the calendar quarter after receipt.

Comment: Some commenters expressed concern that the ASP + 6 percent payment methodology would discourage providers from using generic drugs and would increase the tendency to use newer or more expensive agents.

Response: It is true that the higher the average sales price of a drug, the greater amount of money represented by 6 percent of that price. However, Section 1847A specifies that payment is at 106 percent of ASP. The law requires the use of the new ASP + 6 percent payment system except in the limited instances described below in Sections V and VI.

Comment: Several commenters suggested that we should establish a mechanism to provide the public with an opportunity to identify errors in the ASP-based payment rates before the start of the calendar quarter in which the rates are effective. They believe that this mechanism would minimize errors by permitting posting of the rates several weeks prior to the effective date.

Response: Our goal is to provide as much information on Medicare Part B drug payment rates as possible as early as possible prior to the effective date of those rates.

Comment: A physician specialty group recommended that we use our inherent reasonableness authority to increase drug payments up to 15 percent where necessary to make the Medicare payment level sufficient to cover the price of drugs charged by specialty distributors that service the physician office market.

Response: We do not have sufficient data to determine whether our inherent reasonableness authority would apply in this instance. Even if our inherent reasonableness authority were triggered, our data are insufficient to determine whether the adjustment the commenters request would be appropriate.

Comment: Several commenters urged us to weigh the full range of potential consequences to patient care, especially in the oncology setting, with the implementation of the ASP payment methodology. They recommended that we take into consideration concerns such as the potential inability of providers to purchase drugs below the new reimbursement rate, the inability of oncologists to provide access to important under-reimbursed support services, and the disproportionate impact of these changes on rural providers necessitating a shift in care of sick cancer patient from community settings to the hospital. Some commenters suggested that we place a form on its Web site enabling beneficiaries to identify access problems. One commenter suggested that we perform a 1-year monitoring study to evaluate the quality of care issues and delay implementation until the results of the study are known.

Response: Although we do not expect access problems under the new ASP + 6 percent payment system, we will be monitoring patient access through our 1–800–MEDICARE line, regional office staff, claims analysis, and other environmental scanning activities. We will work with Congress if access issues arise. The law requires that the new ASP-based drug pricing system be implemented January 1, 2005.

Comment: Several commenters expressed concern regarding the statements on joining group purchasing organizations (GPOs) to improve their purchasing power. They indicate that

the size of the discount is based on the individual GPO member's purchases, not the combined purchases of the GPO members. Thus, membership in a GPO would not necessarily result in a greater discount. They also point out that retail pharmacies do not have access to GPO purchasing arrangements. One commenter requested that we offer more tangible suggestions for obtaining drugs at the ASP +6 percent price other than encouraging physicians to participate in purchasing groups.

Response: The law requires that the new ASP-based drug pricing system be implemented January 1, 2006. A recent survey of oncology practices performed by the American Society of Clinical Oncology indicated that the purchase price of drugs is not necessarily driven by practice size. It would appear that smaller purchasers are on average sometimes able to achieve similar drug pricing to larger purchasers. The OIG is conducting a study due not later than October 1, 2005, on the ability of different size physician practices in the specialties of hematology, hematology/oncology, and medical oncology to obtain drugs at 106 percent of the average sales price. We are currently conducting another MMA-mandated study of sales of drugs to large volume purchasers that is due not later than January 1, 2006. We will seek to work with physicians, providers, and suppliers on ways to encourage prudent purchasing, including to the extent practicable the dissemination of information on lower cost suppliers of Medicare Part B drugs. We would welcome suggestions on ways to accomplish this goal.

Comment: One commenter suggested that classes of trade should be taken into account when establishing ASP payment rates.

Response: The law does not permit the exclusion of or differentiation by classes of trade in the calculation of the ASP payment rates, except for the specific statutory exceptions described in the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act. The statute specifies a payment rate of 106 percent of ASP.

Comment: A drug manufacturer urges us to reject any requests to publish the NDC-specific ASPs as the publishing of the rates would facilitate inappropriate conduct.

Response: The law does not permit the disclosure of NDC level ASPs in a form that discloses the identity of a specific manufacturer or prices charged by the manufacturer except in accordance with Section 1927(b)(3)(D) of the Act. That provision permits the disclosure of such data as the Secretary determines to be necessary to effectuate the provisions of section 1847A of the Act.

v. Limitations on ASP

Section 1847A(d)(1) of the Act states that ''The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.'' Section 1847A(d)(2) of the Act states that ''Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

- The widely available market price for such drugs and biologicals (if any); and
- The average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.''

Section 1847A(d)(3) of the Act states that ''The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).'' Section 1847A(d)(3)(B) states that ''the term 'applicable threshold percentage' means—

- In 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and
- In 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.''

Section 1847A(d)(3)(C) of the Act states that ''If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

- The widely available market price for the drug or biological (if any); or
- 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.''

Comment: One commenter urged us to provide further guidance on the widely available market price (WAMP) methodology, specifically how the OIG will compare ASP to WAMP. The commenter also requested guidance on how WAMP will be determined in the case of multiple drugs represented by a single J-code. Other commenters stated that we should provide greater guidance for how it will substitute WAMP for ASP. These commenters also suggested that we provide guidance on how it will treat quarterly oscillations between ASP and WAMP.

Response: The OIG is developing its methodology regarding the widely available market price. Because the determination of WAMP is within OIG's purview, we believe it is premature to address the implementation issues prior to the OIG establishing its methodology and conducting its first review.

Comment: Several commenters recommend that we make adjustments where there is a disparity between the ASP-based payment limit and the physician acquisition cost. These commenters recommended that we raise the payment rate if the WAMP is higher than ASP.

Response: Section 1847A of the Act does not provide authority to increase the ASP-based payment system based on the review of the OIG.

vi. Payment Methodology in Cases Where the Average Sales Price During the First Quarter of Sales Is Unavailable

Section 1847A(c)(4) of the Act states that ''In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—

- The wholesale acquisition cost; or
- The methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.''

Comment: Several commenters requested that we provide guidance on how the payment rate for a new drug in its second calendar quarter will be determined. They recommend that we utilize the same methodology for the 2nd quarter payment as for the 1st quarter; that is, use the WAC or methodologies in effect on November 1, 2003.

Response: Pursuant to section 1847A(c)(4) of the Act, during an initial period (not to exceed a full calendar quarter) where data on prices for sales for a drug are not sufficiently available from the manufacturer to compute an ASP, we will pay based on WAC or the methodologies in effect on November 1, 2003 for a limited period. This time period will start on the date that sales of the drug begin and end at the beginning of the quarter after we receive information from the manufacturer regarding ASP for the first full quarter of sales.

c. Payment for Influenza, Pneumococcal, and Hepatitis B Vaccines

Section 1841(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in subparagraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of the average wholesale price (AWP) of the drug. The AWP payment rates for these vaccines will be updated quarterly. No commenters objected.

d. Payment for Drugs Furnished During 2005 in Connection With the Furnishing of Renal Dialysis Services if Separately Billed by Renal Dialysis Facilities

Section 1881(b)(13)(A)(ii) of the Act indicates that payment for a drug furnished during 2005 in connection with the furnishing of renal dialysis services, if separately billed by renal dialysis facilities, will be based on the acquisition cost of the drug as determined by the Inspector General(IG) report to the Secretary required by section 623(c) of the MMA or, insofar as the IG has not determined the acquisition cost with respect to a drug, the Secretary shall determine the payment amount for the drug. In the report, ''Medicare Reimbursement for Existing End-Stage Renal Disease Drugs,'' the IG found that, on average, in 2003 the four largest chains had drug acquisition costs that were 6 percent lower than the ASP of 10 of the top drugs, including erythropoietin. A sample of the remaining independent facilities had acquisition costs that were 4 percent above the ASP. Based on this information, the overall weighted average drug acquisition cost for renal dialysis facilities is 3 percent lower than the ASP. Therefore, we proposed that payment for a drug or biological furnished during 2005 in connection with renal dialysis services and separately billed by renal dialysis facilities will be based on the ASP of the drug minus 3 percent. We proposed to update this quarterly based on the ASP reported to us by drug manufacturers.

We received numerous comments regarding our proposed payments rate of ASP minus 3 percent. Those comments and responses are provided below.

Comment: Commenters questioned the basis for our decision to pay for separately reimbursed drugs at a rate of ASP minus three percent. These commenters stated that ASP minus 3 percent was not acquisition cost as determined by OIG and did not reflect the acquisition cost relationship between these drugs. Some commenters questioned the relationship between the ASP definition used by the OIG and the current definition. Commenters stated that we should base the payment rates on the acquisition cost of each drug as reported by the OIG updated to 2005 rather than an ASP-based formula. Some commenters indicated that the acquisition cost should be updated to 2005 and suggested an update using the same annual factor used for budget neutrality calculations. For drugs not included in the OIG report, some commenters suggested that we use the same methodology for most other Medicare Part B drugs, namely ASP plus 6 percent. Commenters indicated we should consider two tiers of payment based on provider size to minimize the discrepancy between large and small providers or in the absence of two tiers base the payment on the acquisition cost of the facilities not owned or managed by the four largest providers. Commenters also asked for clarification of the payment basis for separately billable ESRD drugs other than EPO billed by hospital based ESRD facilities since these drugs historically were not paid based on AWP but rather based on reasonable cost.

Response: We agree with the commenters who suggested we base the 2005 payment rates for separately billable ESRD drugs on the actual dollar value of the acquisition costs as determined by the IG rather than the acquisition costs relative to the ASP. We also agree that we should update the IG acquisition costs to calculate 2005 rates. After consideration of the available price data, we have determined that the Producer Price Index (PPI) for prescription preparations is the most appropriate price measure for updating EPO and other separately billable drugs from 2003 to 2005. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) for prescription drugs reflects price changes at the retail stage. Because EPO and many of the separately billable drugs used by dialysis facilities are purchased directly from the manufacturer, the use of a price index that measures wholesale rather than retail prices is more appropriate. The PPI for prescription drugs is the measure used in the various market baskets that update Medicare payments to hospitals, physicians, skilled nursing facilities, and home health agencies. In addition, the PPI for prescription drugs was recommended for use in the proposed composite rate market basket detailed in the 2003 Report to Congress.

Based on historical data through the second quarter of 2004, we used the Global Insight Inc. forecast of the PPI for prescription drugs to determine the update factors for 2004 and 2005. We feel the use of an independent forecast, in this case from Global Insight Inc., is superior to using the Naational Health Expenditure projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases for Medicare prospective payment systems.

We also agree with those commenters who suggested that the drugs not contained in the IG study should be paid at ASP plus 6 percent. We believe it is appropriate for the payment amount for these drugs when separately billed by ESRD facilities during 2005 to be the same as the payment amount for other entities that are paid by Medicare on other than a cost or prospective payment basis. We do not agree with commenters that we should establish separate drug payment rates for large and small providers. For reasons discussed in the section of this final rule on the ESRD composite rate, we believe it is appropriate to establish a single add-on payment to the composite rate and therefore appropriate to establish the same drug payment rates for both large and small providers. We do not believe it is appropriate to base the payment amount on only the higher acquisition cost of the facilities not owned or managed by the four largest providers and not take into account the acquisition costs of the largest four providers who represent the majority of the drug expenditures. Section 1881(b)(13)(A)(ii) of the Social Security Act refers to ''the acquisition cost of the drug or biological'' and not the acquisition costs of the drug or biological. In accordance with the statute and our understanding of Congressional intent for 2005, we believe it is more appropriate to base the 2005 payment amounts on a weighted average of the acquisition costs of the four largest providers and the other

facilities rather than base the 2005 payment amounts solely on the acquisition costs of the other facilities.

In response to the commenters who requested clarification of the payment basis for separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities, we did not propose changes to the reasonable cost payment basis for these drugs. The OIG did not study separately billable ESRD drugs other than EPO billed by hospital-based ESRD facilities and accordingly, we did not propose to change the payment basis for these drugs.

e. Payment for Infusion Drugs Furnished Through an Item of DME

In 2005, section 1841(o)(1)(D)(i) of the Act requires that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent of the average wholesale price for that drug in effect on October 1, 2003. No commenters objected.

2. Drug Administration Payment Policy and Coding Effective in 2005

Section 1848(c)(2)(J) of the Act (as added by section 303(a) of the MMA) requires the Secretary to promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for those services, taking into account levels of complexity of the administration and resource consumption. According to section 1848(c)(2)(B)(iv) of the Act (as amended by section 303(a) of the MMA), any changes in expenditures in 2005 or 2006 resulting from this review are exempt from the budget neutrality requirement of section 1848(c)(2)(B)(ii) of the Act. The statute further indicates that the Secretary shall use existing processes for the consideration of coding changes and, to the extent changes are made, shall use those processes to establish relative values for those services. The Secretary is also required to consult with physician specialties affected by the provisions that change Medicare payments for drugs and drug administration.

The AMA's CPT Editorial Panel established a workgroup, with representatives from affected specialties that met earlier this year to develop recommendations to the CPT Editorial Panel in August. Based on these recommendations, that panel adopted several new drug administration codes and revised several existing codes. Subsequently, the AMA's Relative Value Update Committee (RUC) met at the end of September to make recommendations to us on the practice expense resource inputs and work relative values for the new and revised drug administration codes.

We indicated in the proposed rule that we would consider whether it is necessary for us to make coding changes effective January 1, 2005 through the use of G-codes (because the 2005 CPT book will have already been published), and we requested public comment. As described in detail below, we are establishing new G-codes for 2005 that correspond with the new CPT codes that will become active in 2006. These new G-codes are interim until 2006.

The new CPT codes can be categorized into the following three categories of drug administration services: infusion for hydration; nonchemotherapy therapeutic/diagnostic injections and infusions other than hydration; and chemotherapy administration (other than hydration) which includes infusions/injections. There are some important changes in the new codes relative to current drug administration coding. The infusion of substances such as monoclonal antibody agents or other biologic response modifiers is reported under the chemotherapy codes, instead of the nonchemotherapy infusion codes, as is currently the case. There are also new codes in both the chemotherapy and nonchemotherapy sections for reporting the additional sequential infusion of different substances or drugs.

As we stated in the proposed rule, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue. We also note that the MMA requires the Medicare Payment Advisory Commission (MedPAC) to study how the changes in payments for drugs and drug administration affect other specialties.

We received many comments on various aspects of coding and payment for drug administration services in response to the proposed rule. We are also responding below to comments we received on the January 7, 2004 interim final rule with comment period that announced the provisions of section 303 of the MMA affecting drug administration services that took effect in 2004 (69 FR 1094). Specifically, section 303 of the MMA required the following changes in 2004: a transitional adjustment that increases payments for specific drug administration services by 32 percent in 2004 (and 3 percent in 2005); establishing work RVUs for certain drug administration services equal to the work RVUs for a level 1 office medical visit for an established patient; the incorporation of supplemental survey data in the calculation of the practice expense RVUs for drug administration codes; and allowing oncologists to bill for multiple drug administrations by the ''push'' technique on a single day.

Comment: Many commenters supported the efforts to promptly evaluate existing drug administration codes to ensure accurate reporting and billing for services. They support our proposal to use G-codes until the new CPT codes are active. They asked us to adopt the recommendations of the CPT Editorial Panel for new drug administration codes.

Response: We appreciate the support of the commenters of all of the efforts to expeditiously review and update these codes. We also would like to specifically recognize the efforts of the CPT Editorial Panel's Drug Administration Workgroup to develop the new CPT codes, the Editorial Panel for its consideration and approval of the new codes, and the RUC for its similar efforts to develop recommendations for the inputs for the new codes.

We have reviewed the recommendations of the CPT Editorial Panel and, with one exception noted below, agree with their new and revised codes for drug administration for 2005. Because the new CPT codes will not be included in the 2005 CPT, we have decided to establish G-codes, where applicable. At this time, we anticipate these new G-codes will be temporary until the new CPT codes become active January 1, 2006.

A listing of the old CPT codes and their corresponding G-codes are in the table below. Some of the old CPT codes will correspond to more than one G-code, and there are codes that will allow physicians to bill for services that previously did not have a code or were bundled into other services.

The drug administration codes are divided into three categories: infusion codes for hydration; codes for therapeutic/diagnostic injections; and chemotherapy administration codes. The descriptions of the codes below are taken primarily from the AMA CPT Editorial Panel. We are including these specific descriptions here in order to provide as much information as possible about the new G-codes prior to their implementation on January 1, 2005. However, we anticipate that we will issue further instructions regarding the appropriate use of these G-codes, including clarifications, interpretations, and other modifications to the following guidance (apart from the G-codes

themselves) as part of any instructions issued through a subregulatory process.

The codes for hydration (G0345 and G0346 in the table below) are for reporting hydration intravenous (IV) infusions consisting of a prepackaged fluid and electrolytes. These codes are not used to report infusion of drugs or other substances. The codes for chemotherapy administration are to be used for reporting the administration of non-radionuclide anti-neoplastic drugs, and anti-neoplastic agents provided for treatment of noncancer diagnoses, or substances such as monoclonal antibody agents and other biologic response modifiers. The remaining codes are for reporting injections and infusions for all drug administrations that were previously reported using CPT codes 90780–90788, 96400, and 96408–96414 (other than those described above as hydration or chemotherapy).

TABLE 8: Comparison of old CPT codes to G codes

Hydration

Old CPT	G Code	Descriptor
90780	G0345	Intravenous infusion, hydration; initial, up to one hour
90781	G0346	each additional hour, up to eight (8) hours

Injections and Infusions (Non-Chemotherapy, other than hydration)

Old CPT	G Code	Descriptor
90780	G0347	Intravenous infusion, for therapy/diagnosis, initial, up to one hour
90781	G0349	additional sequential infusion, up to one hour
90781	G0348	each additional hour, up to eight (8) hours
N/A	G0350	Concurrent infusion

Old CPT	G Code	Descriptor
90782	G0351	Therapeutic or diagnostic injection
90783	N/A	intra-arterial
90784	G0353	intravenous push, single or initial substance/drug
N/A	G0354	each additional sequential intravenous push
90788	N/A	Intramuscular injection of antibiotic
90799	N/A	Unlisted injection or infusion

Chemotherapy Administration

Old CPT	G Code	Descriptor
96400	G0355	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96400	G0356	hormonal anti-neoplastic
96405	N/A	Chemotherapy administration; intralesional, up to and including 7 lesions
96406	N/A	intralesional, more than 7 lesions
96408	G0357	intravenous, push technique, single or initial substance/drug
96408	G0358	intravenous, push technique, each additional substance/drug
96410	G0359	Chemotherapy administration, intravenous infusion technique; Up to one hour, single or initial substance/drug
96412	G0360	each additional hour, one to eight (8) hours
96414	G0361	initiation of prolonged chemotherapy infusion
96412	G0362	each additional sequential infusion, up to one hour
96420	N/A	Chemotherapy administration, intra-arterial; push technique
96422	N/A	infusion technique, up to one hour
96423	N/A	infusion technique, each additional hour, one to eight hours

96425	N/A	infusion technique, initiation of prolonged infusion (more than eight hours)
96440	N/A	Chemotherapy administration into pleural cavity
96445	N/A	Chemotherapy administration into peritoneal cavity
96450	N/A	Chemotherapy administration into CNS
96520	N/A	Refilling and maintenance of portable pump
N/A	G0363	Irrigation of implanted venous access device for drug delivery systems
96530	N/A	Refilling and maintenance of implantable pump
96542	N/A	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents

The following coding guidance is based on the CPT Editorial Panel's explanatory language for the new CPT codes. As noted above, we plan to issue further guidance as needed.

Infusions that were previously reported under CPT code 90780 (non-chemotherapy infusion, 1st hour) will be billed under one of three G-codes beginning January 1, 2005. The first hour of a hydration infusion will be billed under G0345. The first hour of infusion of a nonchemotherapy drug other than hydration will be billed under G0347. The first hour of infusion of anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents and other biologic response modifiers is billed under G0359.

Similarly, services that were previously reported under CPT code 90781 (non-chemotherapy infusion, each additional hour) will be billed under one of four G-codes beginning January 1, 2005. Each additional hour of a hydration infusion will be billed under G0346. Each additional hour of a nonchemotherapy infusion will be billed under G0348. Currently, if a second (or other subsequent) nonchemotherapy drug is administered sequentially, the physician would bill code 90781 for the additional hour of infusion. Under the new G-codes, the physician will bill G0349, the sequential administration of a second or subsequent nonchemotherapy drug. In addition, each additional hour of the infusion of anti-neoplastic agents for the treatment of noncancer diagnoses or substances such as monoclonal antibodies and other biological modifiers is billed under G0360.

Injections that were previously billed under CPT code 90782 will now be billed under HCPCS code G0351. Physicians should use HCPCS code G0352 for injections previously billed under CPT code 90783. Nonchemotherapy drugs administered by IV push (currently using CPT code 90784) should now be billed under HCPCS code G0353. The CPT book does not currently contain a code for physicians to bill a second (or other subsequent) nonchemotherapy drug administered by IV push. The CPT Editorial Panel created a new code for each additional nonchemotherapy drug administered by IV push. For 2005, the physician should bill HCPCS code G0354.

The CPT coding system will be deleting code 90788 (Intramuscular injection of antibiotic) in 2006. We are maintaining CPT code 90788 as an active code until it is changed in the CPT coding system and instructions are provided on the code to bill in its place beginning January 1, 2006.

Chemotherapy injections, previously billed under the CPT code 96400, will now be billed using one of two new G-codes. For injection of nonhormonal anti-neoplastic drugs, the physician should bill HCPCS code G0355. For injection of hormonal anti-neoplastic drugs, the physician should bill HCPCS code G0356. CPT is not recommending any changes to CPT codes 96405 (Chemotherapy administration; intralesional, up to and including 7 lesions) and 96406 (more than 7 lesions), and these codes will remain active for Medicare in 2005.

Chemotherapy drugs administered by IV push (currently billed under CPT code 96408, or, if the drug meets the expanded definition of chemotherapy including monoclonal antibodies or other biologic response modifiers, currently billed under CPT code 90784) should be billed using G0357 for the initial drug administered. In 2004, Medicare paid for the second (or other subsequent) chemotherapy drug administered by IV push under CPT code 96408. CPT will be establishing a code that recognizes the resource inputs associated with each additional chemotherapy drug administered by IV push. For 2005, the analogous code to bill the second (or other subsequent) chemotherapy drug administered by IV push is G0358.

The first hour of chemotherapy administration, previously billed under CPT code 96410, should now be billed under CPT code G0359. Each additional hour of chemotherapy (previously billed under CPT code 96412) should now be billed under CPT code G0360. CPT is also recommending a new code for the first hour of a different chemotherapy drug administered sequentially by infusion. If a second chemotherapy drug is administered sequentially, the physician should bill for HCPCS G0362 for the first hour of infusion of the second drug. All additional hours (up to eight total hours) of chemotherapy infusion should be billed using HCPCS code G0360. Prolonged chemotherapy infusions (8 hours or more, previously billed under code 96414) should be billed in 2005 using HCPCS code G0361.

For three codes (G0350, G0354, G0363), the table above has an ''N/A'' listed in the ''Old CPT'' column, meaning there were no CPT codes that existed explicitly for these services. These services will now be billable under the new coding system. For instance, CPT will be establishing a code for a ''concurrent infusion.'' A concurrent infusion refers to the simultaneous infusion of two nonchemotherapy drugs. We are using temporary code G0350 for this service. Code G0350 is an add-on code. It must be reported as an ''add-on'' or with another code and our payment reflects the incremental resources associated with infusing the second drug. For example, if two nonchemotherapy drugs are infused concurrently, the physician bills G0347 for the initial drug infused and G0350 as an add-on.

As indicated above, HCPCS code G0354 is a new code for each additional sequentialnonchemotherapy drug administered by IV push. HCPCS code G0354 is also an add-on code. In general, G0354 will be an add-on to G0353. However, it is possible that a nonchemotherapy drug administered by IV push may follow the administration of a chemotherapy drug administered by IV push, and HCPCS code G0354 would then be an add-on to HCPCS code G0357.

HCPCS code G0363 is a new code for irrigation of an implanted venous access device. There is currently no code to describe this service. Medicare will pay for G0363 if it is the only service provided that day. If there is a visit or other drug administration service provided on the same day, payment for this service is bundled into payment for the other service.

We are creating the following new add-on G-codes: G0346, G0348, G0349, G0350, G0354, G0358, G0360 and G0362. As indicated above, add-on codes must be billed with other codes, and our payment reflects the incremental resources associated with providing the additional service. The initial codes that these add-on codes could potentially be billed with include: G0345, G0347, G0353, G0357 and G0359. If a combination of chemotherapy, nonchemotherapy drugs, and/or hydration is administered by infusion sequentially, the initial code that best describes the service should always be billed irrespective of the order in which the infusions occur.

Comment: In the January 7, 2004 interim final rule with comment, we revised our payment policy for pushes of chemotherapy drugs to allow for payment of multiple pushes of different chemotherapy agents in one day. A commenter asked that we revise our policy for multiple pushes of nonchemotherapy agents, to allow multiple billings on a single day.

Response: The CPT/RUC recommendations address this comment. New codes have been created to account for the resources associated with multiple chemotherapy and nonchemotherapy drugs administered by IV push. HCPCS code G0353 is used for the initial IV push of a nonchemotherapy drug, while HCPCS code G0354 is used for each additional push of a nonchemotherapy drug. For chemotherapy drugs administered by IV push, HCPCS code G0357 is used for the first drug administered, while HCPCS code G0358 is used for each additional drug.

We also note that existing CPT codes 90782–90788 (Therapeutic, prophylactic or diagnostic injections) currently have a status indicator of ''T'', which means that payment for the service is bundled unless it is the only service billed by the physician for the patient that day. However, based on the RUC recommendations and the resulting values for the injection services, we are making the status indicator on HCPCS codes G0351—G0354 an ''A'', which will allow them to be separately paid even if another physician fee schedule service is billed for the same patient that day.

Comment: A commenter stated that, given the increased work and practice expense RVUs for drug administration codes, it follows that both the work and practice expense RVUs for the immunization administration codes (90471, 90472, 90473, and 90474) should also be increased. The commenter argued that the service involved in administering vaccines is more intense/complex than the service involved in the drug infusion codes.

Response: We agree with the commenter that the physician work and practice expenses associated with administering injections are similar to immunizations. In addition, we would point out that we currently pay for vaccine administrations (G0008–G0010) based on crosswalking the RVUs to CPT code 90471. Therefore, any changes to the physician work and practice expense RVUs for code 90471 would also affect payments for vaccine administrations.

Because we agree these services should be similar in the amount of physician work involved, we are assigning the physician work value recommended by the RUC for code 90782 (G-code G0351) to code 90471 and HCPCS G-codes G0008–G0010. We are combining the utilization data for all of these codes to determine a single practice expense RVU that will be applied to each of these codes.

We are also assigning a work RVU of 0.15 to code 90472. Codes 90473 (Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)) and 90474 (Each additional vaccine (single or combination vaccine/toxoid)) are currently not covered. We are changing the status of these codes to ''R'', or restricted, meaning they are payable under some circumstances after carrier review. These codes will be carrier priced.

Comment: If a patient receives chemotherapy infusions, CPT code 96410 is used to report the infusion of the first drug up to one hour. Chemotherapy drugs are usually administered sequentially. Thus, if a patient receives the administration of a second chemotherapy drug at the same treatment session, CPT code 96412 is used to report the infusion of the second drug for each additional hour of infusion. In 2004, the national payment, including the transitional payment adjustment of 32 percent, for CPT code 96410 is $217. The comparable payment for CPT code 96412 is $48.

Commenters pointed out that this policy does not take into account the levels of complexity of administration and resource consumption. The administration of multiple drugs requires additional preparation time, supplies, and patient education, not currently accounted for in CPT code 96412.

Response: The CPT/RUC recommendations addressed this issue. We are implementing new code G0362, Chemotherapy administration, intravenous technique; each additional sequential infusion, up to one hour. This code will allow, effective January 1, 2005, physicians to begin to bill for the first hour of chemotherapy of the second chemotherapy drug administered.

Comment: Several commenters requested clarification that the changes to the drug administration codes resulting from the CPT changes and our G-codes would be exempted from budget neutrality by the provision at section 1848(c)(2)(B)(iv)(III), as added by MMA section 303(a)(1). This provision stipulates that the evaluation of the existing drug administration codes described above as leading to the interim G-codes and the new CPT codes for 2006, is to be exempt from budget neutrality.

Response: The commenters are correct that the additional expenditures that result from the interim G-code changes we are implementing in this rule are exempt from budget neutrality.

Comment: Several commenters asked that we continue payment for drug administration codes at the 2004 levels, which included the 32 percent transitional payment adjustment, instead of paying at the 3 percent transitional payment adjustment for 2005, or adopt other measures. For example, commenters suggested temporary codes to offset the large reductions that would otherwise go into effect in 2005.

Response: Section 303(a)(4) of the MMA is very specific on the application of the transitional payment adjustments in 2004 and 2005. We do not have the legal authority to continue payments based on the 2004 payment levels. In 2005, the transitional adjustment percentage for drug administration

decreases from 32 percent to 3 percent. No transitional percentage is applied in 2006 or subsequent years.

Comment: One commenter requested additional temporary G-codes to offset the payment reductions for oncologists that would otherwise go into effect in 2005. According to this commenter, the payment amount associated with each of these codes would be a percentage add-on amount sufficient to offset the reductions in drug margins and payments for drug administration services.

Response: We have worked extensively with the major associations representing oncologists and their patients to ensure that Medicare continues to pay appropriately for these extremely critical services. The payment changes we made for 2004, the new G-codes, and allowing additional payment for injections and additional infusions, either have already increased, or will increase, payments for drug administration services. The impacts of these changes are discussed extensively in the impact analysis section of this final rule.

In addition, as we indicated above, we plan to analyze any shift or change in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect. While we do not believe the changes will result in access problems, we plan to continue studying this issue.

Comment: One commenter expressed concern that the reductions in payments to oncologists described in the proposed rule could make it difficult, if not impossible, for many patients to continue to access cancer care in nonhospital community settings.

Response: As noted above, we have taken several steps to increase payments for drug administration services in this final rule. We recognize that oncology patients in the Medicare population undergoing chemotherapy face serious and unique issues and problems related to quality of care throughout the life cycle of their disease process; from the time of first diagnosis, through treatment, until the patient experiences an end to medical (including hospice) care. Patients, national cancer organizations, and medical providers have identified certain factors that they believe affect the comfort and ultimately the care for cancer patients in the physician office setting.

We believe that the goals and objectives of optimal treatment include reviewing and analyzing pain control management, minimization of nausea and vomiting, explaining treatment options, outlining existing chemotherapy regimens, assessing quality of life, assessing patient symptoms and complaints, supporting and educating caregivers, and avoidance of unnecessary Emergency Department visits and inpatient hospitalizations. Further, we believe that clinicians armed with appropriate assessments can proactively intervene with medical treatment and nonmedical assistance to help ameliorate some of the distressing and unpleasant, but frequent and predictable, events that may accompany certain cancers and chemotherapeutic regimens used to combat cancer.

The Secretary has been given the authority under sections 402(a)(1)(B) and 402(a)(2) of the Social Security Act Amendments of 1967 (Pub. L. 90–248), as amended, to develop and engage in experiments and demonstration projects to provide incentives for economy, while maintaining or improving quality in provision of health services. In order to identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population, we will initiate a one-year demonstration project for CY 2005. While we encourage optimal care in all facets of treatment, the focus of the demonstration project will be on three areas of concern often cited by patients: pain control management, the minimization of nausea and vomiting, and the reduction of fatigue.

Practitioners participating in the project must provide and document specified services related to pain control management and minimization of nausea and vomiting, and the reduction of fatigue. To facilitate the collection of this information, we have established 12 new G-codes to be reported by program participants.

G-Codes for Assessment of Nausea and/or Vomiting

G9021: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level one: not at all (for use in a Medicare-approved demonstration project).

G9022: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level two: a little (for use in a Medicare-approved demonstration project).

G9023: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level three: quite a bit (for use in a Medicare-approved demonstration project).

G9024: Chemotherapy assessment for nausea and/or vomiting, patient reported, performed at the time of chemotherapy administration; assessment level four: very much (for use in a Medicare-approved demonstration project).

G-Codes for Assessment for Pain

G9025: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare-approved demonstration project).

G9026: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare-approved demonstration project).

G9027: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration assessment level three: quite a bit (for use in a Medicare-approved demonstration project).

G9028: Chemotherapy assessment for pain, patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project).

G-Codes for Assessment for Lack of Energy (Fatigue)

G9029: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level one: not at all (for use in a Medicare approved demonstration project).

G9030: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level two: a little (for use in a Medicare approved demonstration project).

G9031: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level three: quite a bit (for use in a Medicare approved demonstration project).

G9032: Chemotherapy assessment for lack of energy (fatigue), patient reported, performed at the time of chemotherapy administration, assessment level four: very much (for use in a Medicare-approved demonstration project).

The codes correspond to four patient assessment levels (''not at all,'' ''a little,'' ''quite a bit,'' or ''very much'') for each of the following three patient status factors: nausea and/or vomiting;

pain; and lack of energy (fatigue). These levels, based on the Rotterdam scale, were chosen since they appear to be less burdensome for the practitioner and more easily understood by the patient. Participating practitioners must bill the applicable G-codes for each patient status factor (that is, one G-code each for patient comfort assessment factors: nausea and/or vomiting; pain; and fatigue) assessed during a chemotherapy encounter in order to receive payment under the demonstration. A G-code for each patient status factor must appear on the claim for payment to be made under the demonstration project. A patient chemotherapy encounter is defined as chemotherapy administered through intravenous infusion or push, limited to once per day. During the course of the demonstration, an additional payment of $130 per encounter will be paid to participating practitioners for submitting the patient assessment data as described above.

Any office-based physician or nonphysician practitioner operating within the State scope of practice laws who takes care of and administers chemotherapy to oncology patients in an office setting is eligible to participate in this demonstration project. By billing the designated G-codes, the practitioner self-enrolls in the project and agrees to all of the terms and conditions of the demonstration project.

This information will help us to work with those who care for cancer patients to determine ways to improve the quality of care and quality of life for patients as demonstrated by measuring objective parameters and the medical response to those standardized measurements. The evaluation of the project will be based on data reported to us by the practitioners and the use of our administrative claims data to examine Emergency Department visits and inpatient hospitalizations.

We anticipate that further information regarding this demonstration project will be forthcoming after publication of this final rule.

Comment: Commenters pointed out that, under the MMA, we added physician work RVUs to specified drug administration codes equivalent to a level 1 established office visit. They indicated that we should also have increased the practice expense inputs for the same drug administration codes to account for the practice expense inputs associated with a level 1 established office visit.

Response: Section 1848(c)(2)(H)(iii) of the Act (as added by 303(a)(1)(B) of the MMA) specified that we increase the work RVUs for drug administration services equal to the work RVUs for a level 1 established patient office visit (CPT code 99211). As indicated in the January 7, 2004 **Federal Register** (69 FR 1093), we established work RVUs of 0.17 for specific CPT codes that met the statutory definition of ''drug administration services.''

However, the legislation did not direct us to also increase the practice expense RVUs of the drug administration codes to include the clinical staff time associated with a level 1 office visit. The practice expense inputs of the existing CPT codes for drug administration were refined in 2002. We believe the recommendations from the PEAC included the typical clinical staff time associated with each drug administration service.

The CPT Editorial Panel approved new and revised codes for drug administration services for 2005. Depending upon the service, the RUC is recommending work RVUs for the new drug administration codes that may equal, exceed or be less than 0.17. Although section 1848(c)(2)(H)(iii) of the Act requires that the work RVUs for drug administration services shall equal those of a level 1 office medical visit, new subparagraph (J) requires the Secretary to ''promptly evaluate existing drug administration codes for physicians' services''. The statute further indicates that the ''Secretary shall use existing processes for the consideration of coding changes and * * * in establishing relative values * * *''

Because we typically use the CPT and RUC processes to establish codes and relative values, we believe the statute gives us authority to establish work RVUs at a level other than those of a level 1 established patient office visit. Therefore, for 2005, we are accepting the RUC recommendations for the interim G-codes even though they result in work RVUs that are different than 0.17.

Comment: Several organizations and physicians commented that the Medicare payments for the chemotherapy codes do not include payment for many services provided by an oncology practice. These services include support services such as nutrition counseling, social work services, case management, psychosocial counseling, and educational services provided by an oncology nurse to the patient.

Response: Under certain circumstances, Medicare does make explicit payment for clinical social worker and medical nutrition therapy services. Medicare can pay separately for the services of clinical psychologists (CPs), clinical social workers (CSWs), and nurse practitioners (NPs), clinical nurse specialists (CNS) and physician assistants (PAs).

CPs can bill directly for services and supplies they are legally authorized by the State to perform that could also be furnished by a physician or incident to a physician's service. Payment for CP services is made at 100 percent of the physician fee schedule for services they are authorized to provide that are comparable to those of a physician.

CSWs can furnish services for the diagnosis and treatment of mental illnesses that they are legally authorized by the State to provide. Payment for CSW services is made at 75 percent of the CP fee schedule, which is 100 percent of the physician fee schedule.

NPs, CNSs and PAs can bill for mental health services consistent with their authority under law to furnish physician services. They may also bill for services furnished incident to their own professional services that fall under the State scopes of practice. Payment for these services is made at 85 percent of the physician fee schedule. Medicare will pay for medical nutrition therapy services provided by a registered dietitian or nutrition professional for a beneficiary with diabetes or renal disease. Based on a comment on our August 20, 2003 proposed rule (68 FR 50428), we understand that social worker services could involve different tasks (''helping patients with their health insurance, filling and refilling prescriptions'') than those that are explicitly paid for by Medicare. However, we believe Medicare does pay for these services indirectly through the practice expense RVUs for drug administration services. If these services are typically provided to cancer patients, we believe the RUC could consider whether it is possible for resource inputs for these types of staff to be incorporated into the new drug administration codes. We also believe that the RUC could consider whether these types of staff activities are unique to physicians who provide drug administration or if they apply to other physicians' services as well.

Comment: Current CPT code 96412 (infusion techniques, one to 8 hours, each additional hour) is an add-on code, billed in addition to the primary code, 96410 (the first hour of chemotherapy). There is no national coding policy that explains how this add-on code is to be reported if less than a full hour of chemotherapy infusion is provided. A commenter pointed out that the Medicare carriers have different policies for reporting this service. Some carriers require the infusion to extend at least 16 minutes into the subsequent hour before

an add-on code can be billed, and others impose a 31 minute requirement. The commenter asked that we establish a uniform policy for the carriers to follow.

Response: The CPT Editorial Panel addressed this issue as part of its review of the drug administration codes. Effective in 2006, the add-on code is to be used for ''infusion intervals of greater than thirty minutes beyond one hour increments''. We are adopting this policy for chemotherapy administration codes furnished on or after January 1, 2005.

Comment: The nonchemotherapy subcutaneous injection is currently reported and paid under CPT code 90782, while a chemotherapy subcutaneous injection is currently reported under CPT code 96400. Some commenters recommended that we permit billing for nonchemotherapy injections for cancer patients to be made under CPT code 96400. They believe this code more appropriately reflects the practice expenses related to supportive care for chemotherapy.

Response: The CPT Editorial Panel explicitly addressed this issue by creating separate drug administration codes for hydration, nonchemotherapy infusions and injections, and chemotherapy infusions and injections. It further expanded the definition of chemotherapy to include those drugs where the resource costs associated with the drug administration are similar to those administered as anti-neoplastics. Other drugs administered in support of chemotherapy, such as anti-emetics and drugs to prevent anemia, are billed using the injection code, G0351, which replaces CPT code 90782 (consistent with the CPT recommendations). We have reviewed the practice expense inputs for this code from the RUC and accepted their recommendation.

Comment: Some commenters asked that complex non-oncology infusions, such as Remicade, be paid at the same level as chemotherapy infusions. They indicate that these nonchemotherapy infusions have similar complexity and resource use as chemotherapy infusions.

Response: The CPT recommendations address this issue. The codes for chemotherapy administration are for reporting the administration of non-radionuclide, anti-neoplastic drugs, anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents, and other biologic response modifiers.

Comment: Some commenters inquired about the recognition of a severe drug reaction management code that could be used during the administration of high complexity biologic medications and less frequently during other drug administrations or chemotherapy services. While the CPT Drug Administration Workgroup supported the creation of a severe drug reaction management code, the CPT Editorial Panel did not approve this code.

Response: We recognize that considerable physician effort may be required to monitor and attend to patients who develop significant adverse reactions to chemotherapy drugs, or otherwise have complications in the course of chemotherapy treatment. Physicians may not be aware that these services can be billed using existing CPT codes. The following scenarios are examples where existing codes may be used in addition to the routine billing for the physician's care of a cancer patient:

- Bill for the Physician Visit. If a patient has a significant adverse reaction to drugs during a chemotherapy session and the physician intervenes, the physician could bill for a visit in addition to the chemotherapy administration services.
- Bill for the Higher-Level Physician Visit. If the patient had already seen the physician prior to a chemotherapy session for a problem that is unrelated to the supervision of the administration of chemotherapy drugs, the physician may bill a visit for a significant adverse drug reaction. The total time, resources, and complexity of the physician's interaction with the patient may justify a higher level of visit service.
- Bill for a Prolonged Service. If the patient had a physician visit prior to the chemotherapy session and experienced a significant adverse reaction to drugs on the same day, the physician can bill a prolonged service code in addition to the physician visit. There are several code combinations to use depending on the number of minutes involved. The physician must have a face-to-face encounter with the patient and must spend at least 30 minutes beyond the threshold or typical time for that level of visit for the physician to bill for the prolonged service code.
- Bill for Critical Care Service. If the patient had a physician visit prior to the chemotherapy session and experienced a life-threatening adverse reaction to the drugs, the physician could bill for a critical care service in addition to the visit if the physician's work involves at least 30 minutes of direct face-to-face involvement managing the patient's life-threatening condition. Examples of life-threatening conditions are: central nervous failure, circulatory failure, shock, renal, hepatic, metabolic, and/or respiratory failure.

These instructions are published here for informational purposes, and we anticipate that we will issue further instructions regarding the appropriate use of these G-codes including clarifications, interpretations and other modifications to the following guidance as part of any instructions issued through a subregulatory process.

Comment: The American Urological Association (AUA) commented in response to the January 7, 2004 interim final rule to ask us to include the following codes in the MMA-mandated evaluation of existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services: CPT codes 11980, 11981, 11982, 11983, 51700, 51720, 54200, 54231, and 54235. The AUA asked that we consider applying the transitional adjustment payment to these codes for 2005.

Response: We presented these codes to the CPT Drug Administration Workgroup. After subsequent discussion with representatives of the AUA, the AUA withdrew these codes from consideration by the workgroup.

These codes are not subject to the ''transitional adjustment payment provision'' because they are not included in the definition of ''drug administration codes.''

Comment: Ophthalmologists frequently perform the procedure photodynamic therapy (CPT code 67221 and 67225) by infusing the drug Visudyne. While separate payment is allowed for the drug, the infusion is considered an integral part of the photodynamic therapy code. Thus, the physician is not allowed to bill a separate code for the infusion of the drug.

According to one commenter, Visudyne is also a drug used in cancer chemotherapy. The commenter pointed out that when Visudyne is provided for photodynamic therapy, ophthalmologists incur drug administration costs similar to oncologists who use infused drugs.

The AAO asked why we did not include CPT codes 67221 and 67225 among the drug administration codes that benefited under the MMA.

Response: In this instance, the infusion of the drug is an integral part of the surgical procedure and it was valued by the RUC and CMS that way. The code of which it is a part is not considered a drug administration code under section 303 of the MMA.

3. Blood Clotting Factor

For clotting factors furnished on or after January 1, 2005, we proposed to establish a separate payment of $0.05

per unit to hemophilia treatment centers, homecare companies and other suppliers for the items and services associated with the furnishing of blood clotting factor. Section 303(e)(1) of the MMA requires the Secretary, after review of the January 2003 report to the Congress by the Comptroller General of the United States, to establish a furnishing fee for the items and services associated with the furnishing of blood clotting factor.

Based on a review of the Government Accountability Office (GAO) report and data received from various clotting factor providers, we proposed a furnishing fee in order to cover the administrative costs associated with supplying the clotting factor. As outlined in the MMA, any separate payment amount established may include the mixing and delivery of factors, including special inventory management and storage requirements, as well as ancillary supplies and patient training necessary for the self-administration of these factors. The MMA states that, in determining the separate payment, the total amount of payments and these separate payments must not exceed the total amount of payments that would have been made for the factors if the amendments in section 303 of the MMA had not been enacted.

As indicated in the GAO report, ''[w]hen Medicare's payment for clotting factor more closely reflects acquisition costs, we recommend that the Administrator establish a separate payment for providers based on the costs of delivering clotting factor to Medicare beneficiaries.'' Effective upon implementation of the ASP-based payment rates, payment for blood clotting factors will more closely reflect acquisition costs, since payment will be based on the average sales price as reported by drug manufacturers plus 6 percent.

Therefore, we stated in the August 5, 2004 proposed rule that in the absence of additional data we believe that a furnishing fee of $0.05 per unit for the cost of delivering clotting factor is an appropriate amount. However, we also sought updated data and comments on the GAO report, as well as information on the fixed and variable costs of furnishing clotting factor. We recognized that there may be alternatives to a fee, which varies entirely based on the number of units of clotting factor furnished. We indicated we would closely examine all data and information submitted in order to make a final determination with respect to the appropriateness of the $0.05 per unit amount.

We received comments from various sources including, but not limited to, hemophilia treatment centers, hemophilia coalitions, and other suppliers of clotting factors regarding our request for additional data and information on the appropriateness of our proposed fee. The comments and responses are provided below.

Comment: Many commenters recommended that we incorporate cost information received from homecare providers and any updated cost data from hemophilia treatment centers in determining the separate furnishing fee payment amount for 2005. The commenters cited an industry-sponsored survey of full-service hemophilia homecare companies that recommended a furnishing fee of $0.20 per unit. This survey collected CY 2003 data from three hemophilia homecare suppliers that the commenter indicated supplied 42 percent of all Medicare hemophilia patients. Commenters also stated that the GAO report was inadequate to serve as the basis for determining the separate payment for clinically appropriate items and services related to furnishing blood clotting factor. They questioned the accuracy of the recommended payment range in the GAO report, given what they viewed as an insufficient sample size; that is, the GAO report received data from only 4 hemophilia treatment centers and lacked any cost data from national or regional full-service hemophilia homecare providers. These commenters also indicated that the GAO survey may have included homecare companies that purchase clotting factor at a lower price through the Public Health Service's 340B program. More information on the 340B program is available on the Health Resources and Services Administration's Web site at *http://bphc.hrsa.gov/opa/howto.htm.* The commenters also stated that the GAO report focused solely on estimating providers' blood clotting factor delivery costs, which the GAO defined as inventory management, storage, shipping, and the provision of ancillary supplies. According to the commenters, the MMA directed us to establish a separate payment for items and services related to the furnishing of blood clotting factor that takes into consideration a wider range of items and services than the delivery costs addressed in the GAO report, for example patient education.

Response: We agree with the commenters that full-service hemophilia homecare companies provide services that may be of benefit to Medicare beneficiaries with hemophilia, such as disease and patient management activities. However, we do not believe that the scope of the furnishing fee includes these services. As noted above, Section 303(e) specifies the items and services that may be taken into consideration in setting the furnishing fee. Disease and patient management activities are not included in the items and services specified in Section 303(e). However, these activities may be more appropriately addressed through a future phase of the new Medicare Chronic Care Improvement Program.

The new Medicare Chronic Care Improvement Program is an important component of the MMA and demonstrates a commitment to improving and strengthening the traditional fee-for-service Medicare program. This program is the first large-scale chronic care improvement initiative under the Medicare fee-for-service program. We will select organizations that will offer self-care guidance and support to chronically ill beneficiaries. These organizations will help beneficiaries manage their health and adhere to their physicians' plans of care, and help ensure that they seek or obtain medical care that they need to reduce their health risks. More information regarding this program is available on the CMS Web site at *http://www.cms.hhs.gov/medicarereform/ccip/.*

With regard to the other costs identified in the comments and in the industry-sponsored survey, we also do not believe the scope of a furnishing fee includes costs associated with sales and marketing. We do not believe it is appropriate to build an explicit profit margin into the furnishing fee, but rather have the margin associated with the furnishing fee result from efficient furnishing of clotting factor. We agree with the commenters that the GAO report did not include amounts for education and that these are appropriate for the furnishing fee. Therefore, after removing the costs associated with sales and marketing, an explicit profit margin, and patient management, the resulting figure from the homecare survey is $0.14 per unit of clotting factor. We are establishing the furnishing fee for 2004 at $0.14 per unit of clotting factor. For years after 2005, the MMA specifies that the furnishing fee for clotting factor must be updated by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

Comment: One commenter recommended that the beneficiary's 20 percent coinsurance not be applicable to this separate payment. The commenter indicated that the additional financial

burden would limit many beneficiaries' access to this lifesaving product.

Response: Under provisions designed to protect the Medicare program from fraud and abuse, a broad waiver of beneficiary cost sharing of the type the commenter recommends would not be permitted. However, we make no statement regarding the applicability of existing statutory and regulatory provisions that may allow for the waiver of cost sharing in certain cases.

4. Supplying Fee

Section 1842(o)(6) of the Social Security Act requires the Secretary to pay a supplying fee (less applicable deductible and coinsurance) to pharmacies for immunosuppressive drugs described in section 1861(s)(2)(J) of the Act, oral anticancer chemotherapeutic drugs described in section 1861(s)(2)(Q) of the Act, and oral anti-emetic drugs used as part of an anticancer chemotherapeutic regimen described in section 1861(s)(2)(T) of the Act, as determined appropriate by the Secretary. In the interim final rule published on January 7, 2004 (69 FR 1084), we considered this fee to be bundled into the current payment for these drugs for 2004 and did not establish a separately billable supplying fee.

Effective January 1, 2005, we proposed to establish a separately billable supplying fee of $10 per prescription for immunosuppressive drugs, oral anti-cancer chemotherapeutic drugs and oral anti-emetic drugs. We based this proposed fee on information provided by retail chain pharmacies on the costs of supplying these drugs to non-Medicare patients combined with steps to reduce the administrative burden associated with billing Medicare.

We also sought data and information on the additional services pharmacies provide to Medicare beneficiaries, the extent to which oral drugs can be furnished without these additional services and the extent to which such services are covered under Medicare. Additionally, we requested comments concerning whether the supplying fee should be somewhat higher during the initial month following a Medicare beneficiary's transplant to the extent that additional resources are required for example, due to more frequent changes in prescriptions for immunosuppressive drugs.

Comment: Several commenters stated that they were not in a position to determine whether the proposed $10.00 supplying fee was adequate since they did not know the actual 2005 payment rates for Part B drugs. These commenters indicated that the supplying fee needed to cover return on investment, the costs of supplying the drugs, and make up for any differences between the product costs and the ASP based payment for the drug. Some commenters indicated that aside from the adequacy of the ASP-based payment for the drug, a $10.00 supplying fee appeared to be too low. These commenters indicated that the average cost to a retail pharmacy to dispense a non-Medicaid third party or cash paying prescription ranges anywhere from $7.50–$8.00. The commenters indicated that Medicare should pay at least $2.00–$2.50 more per prescription since costs associated with supplying Medicare prescriptions are higher.

We received a comment from a large retail pharmacy indicating that a supplying fee of $25 would be adequate to cover the higher costs of dispensing Medicare Part B oral drugs.

We received comments from specialty immunosuppressive pharmacies that included information from a recent survey of their supplying costs. The survey indicated that the cost for specialty pharmacies to dispense Medicare Part B immunosuppressants is $35.48 per prescription. The specialty immunosuppressive pharmacies indicated that they provide services not typically provided by retail chain drug stores or large mail-order pharmacy benefit management companies. These services include direct patient care through pro-active pharmacist contact, expeditious processing and turnaround of medication orders, direct billing of Medicare and coordination of benefits on behalf of transplant patients to reduce the costs to the patients, and maintaining expensive immunosuppressant in stock to ensure timely receipt when needed by beneficiaries. These pharmacies also indicated that the retail chains typically do not supply immunosuppressive drugs or file Medicare claims.

Several commenters indicated that the lack of on-line adjudication for Medicare claims was one of the major drivers, among other reasons, for the additional costs of supplying Medicare prescription.

Response: We agree that the cost of supplying Medicare Part B oral drugs is higher than many other payers because of the lack of on-line adjudication for Medicare Part B oral drug claims. Due to operational issues, we do not anticipate the establishment of an on-line adjudication system in the near future. Accordingly, we believe it is appropriate to establish a supplying fee higher than the fees paid by some other payers with on-line adjudication. We note that many other payers with on-line adjudication have fees in the range of $5–$10 per prescription. We note that this is consistent with the approximately $8 cost for non-Medicaid dispensing stated by some commenters and described earlier. Other than administrative costs associated with billing Medicare Part B for oral drugs, we do not agree with commenters that the supplying fee for these drugs should exceed the dispensing fees of other payers because we do not believe there are other significant differences between supplying Medicare Part B and other oral drugs. We also do not agree that the supplying fee should include product costs. Product costs are paid through the ASP + 6 percent drug payment system. For the additional burden associated with billing Medicare Part B for oral drugs, we note the commenters who suggested an additional fee of approximately $2 for Medicare billing costs. Added to the $8 non-Medicaid fee described above, this would result in a supplying fee of approximately $10. We also note the survey of the specialty immunosuppressive pharmacies that indicated Medicare claims processing costs of approximately $8. This same survey also indicated total personnel costs of approximately $9, a portion of which we assume is attributable to the additional work associated with Medicare billings because the comments indicated Medicare billing was labor-intensive. Using the $5 to $10 figures for payers with on-line adjudication described above, the specialty pharmacy data on Medicare claims processing costs and personnel costs, we developed a range of possible supplying fees based on the specialty pharmacy data. Depending upon the portion of the personnel costs associated with Medicare billings, this would result in a supplying fee between a minimum of $13 (= $5 + $8) and a maximum of $27 (= $10 + $8 + $9). The comment of the large chain pharmacy recommending a $25 supplying fee indicated that this amount would be adequate to cover the costs of supplying Medicare Part B drugs including the additional costs of processing Medicare claims; however, this amount included a margin for profit. We do not believe it is appropriate to build an explicit profit margin into the supplying fee, but rather have the margin associated with the supplying fee result from efficient supplying of these drugs. Although the profit margin included in the $25 was not explicitly stated in the comment, if we assume a 5 percent margin, then a supplying fee of approximately $24 would cover the large chain pharmacy's

costs of supplying Medicare Part B drugs. We are not indicating that 5 percent is an appropriate margin.

There was variability in the submitted comments with respect to an appropriate supplying fee. On the low end, analysis of the submitted comments would indicate a supplying fee of $10. On the high end, the analysis would indicate a supplying fee of $27. Given the variability in the values and assumptions included in various calculations, we do not think it is appropriate to simply take the rounded midpoint of this range, $19, as the supplying fee. However, we do not think it appropriate to take the maximum amount of this range, $27, given that it is unlikely that all of the personnel costs indicated in the specialty pharmacy survey are related to the costs of billing for oral Medicare Part B drugs. The amount in the comment from the large chain pharmacy, after adjusting for a possible profit margin, or $24, is consistent with our belief that not all of the additional personnel costs identified in the specialty pharmacy survey are related to the costs of billing for oral Medicare Part B drugs. We are therefore establishing a per prescription supplying fee of $24 as the value consistent with both the large retail pharmacy comment (after making an adjustment for built-in profit margins) and the higher end of the broad range of the specialty pharmacy survey. Although we believe that a $24 supplying fee coupled with the ASP-based drug payment will not result in any access problems for Medicare beneficiaries, we will monitor access as we implement the new ASP-based payment system.

Comment: Some commenters recommended that we update the supplying fee annually. Some commenters indicated this fee should be updated by the average annual increase in the costs of pharmacies supplying these drugs to Medicare beneficiaries (costs such as rent, utilities and salaries), but no less than the increase in the medical care inflation index for the most recent twelve months for which it can be calculated before the next calendar year.

Response: We will study the issue of appropriate future increases for the supplying fee and proceed, as necessary, through notice and comment rulemaking.

Comment: A specialty organization suggested that we develop a sliding supplying fee, which would be calculated as a percentage of the cost that the pharmacy incurred in acquiring a particular drug.

Response: We do not agree that the supplying fee should vary by product costs. Product costs are paid through the ASP-based drug payment system.

Comment: Several commenters agreed with our suggestion to increase the supplying fee in the first month following a transplant, but recommended that we extend this increase to at least the first 3 months following the transplant. One commenter suggested that extra resources are associated with frequent changes in prescriptions during the initial month following a beneficiary's organ transplant. One commenter recommended a fee of $50 for an initial prescription fill. However, one commenter advocated against a supplying fee that distinguished between new and refill prescriptions stating that it would be impractical, of questionable benefit and would discourage long-term pharmacy-patient relationships as pharmacy providers would only have an incentive to serve patients in the short term.

Response: We agree that additional costs are most likely to occur nearer the time when the beneficiary has a transplant. In order to recognize these costs, we are establishing a higher supplying fee of $50 for the supplying of the initial oral immunosuppressive prescription in the first month after a beneficiary has a transplant because the costs of supplying immunosuppressives are likely to be higher immediately following a transplant, when the practitioner is adjusting the dose of immunosuppressive drugs. With regard to the comment opposing higher supplying fees for new patients regardless of their transplant date, we agree with the commenter that it would result in inappropriate incentives and are not implementing any such fee.

Comment: Commenters recommended that the supplying fee should account for the different prices paid by pharmacies and physicians, recognizing that these are separate classes of trade that may not have access to comparable pricing. Thus, we should increase the supplying fee associated with providing and overseeing the use of oral anti-cancer drugs.

Response: We do not agree that the supplying fee should vary by product costs. Product costs are paid through the ASP based drug payment system.

Comment: Commenters recommended that we extend the supplying fee to physicians that directly supply covered oral anti-cancer, immunosuppressive and oral anti-emetic drugs to patients, as well as create a dose management and compliance fee for physicians that prescribe oral chemotherapy products. These commenters state that we could use the premise that the MMA does not provide a definition of the word ''pharmacy'' and we could permit payment of a supplying fee to include a physician acting in the capacity of a pharmacist. Alternatively, commenters suggested that we use its inherent reasonableness authority to extend the supplying fee to physicians.

Response: Given our current understanding of Congressional intent, we do not believe it would be appropriate to pay a supplying fee to physicians. Moreover, we do not have sufficient data to determine whether our inherent reasonableness authority would apply in this instance. However, we will study these issues further.

5. Billing Requirements

In the proposed rule, we proposed the following changes to certain billing requirements and clarified policy for other billing requirements in an effort to reduce a pharmacy's costs of supplying covered immunosuppressive and oral chemotherapy drugs to Medicare beneficiaries:

• *Original signed order.* We clarified Medicare's policy regarding the necessity of an original signed order before the filling of a prescription. According to the Medicare Program Integrity Manual (section 5.1 of Chapter 5), which addresses the ordering requirement for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), including drugs, most DMEPOS items can be dispensed based on a verbal order from a physician. A written order must be obtained before submitting a claim, but that written order may be faxed, photocopied, electronic, or pen and ink. The order for the drug must specify the name of the drug, the concentration (if applicable), the dosage, and the frequency of administration. The clarification of this requirement should reduce a pharmacy's costs of supplying covered immunosuppressive and oral drugs to Medicare beneficiaries to the extent that pharmacies are currently applying an original signed prescription requirement.

Comment: Commenters recommended that a prescription be filled and billed based solely on a verbal order from a physician and an actual signed written prescription should not be necessary before billing.

Response: The policy that allows dispensing based on a verbal order but requires a written order for billing applies to all DMEPOS items. This policy balances fraud and abuse concerns with prompt dispensing of DMEPOS items to beneficiaries. We

point out that the written order from the physician can be faxed, photocopied, electronic, or pen and ink. We currently allow pharmacies to accept electronic prescriptions from physicians.

• *Assignment of Benefits Form.* We proposed to eliminate use of the Assignment of Benefits form for Part B items and services, including drugs, where Medicare payment can only be made on an assigned basis. For Part B covered oral drugs, this would be a means of reducing a pharmacy's costs of supplying these drugs to Medicare beneficiaries. Currently, pharmacies must obtain a completed Assignment of Benefits form in order to receive payment from Medicare. This requirement increases a pharmacy's cost of supplying covered drugs to Medicare beneficiaries, as other payers do not impose this requirement. Thus, we do not believe that it is necessary for an assignment of benefits form to be filled out for drugs covered under Part B, since payment for them can only be made on an assignment-related basis.

Comment: Some commenters suggested that the Assignment of Benefits form be eliminated for diabetic supplies dispensed by pharmacy suppliers.

Response: Our proposal to eliminate the Assignment of Benefits form applied to services where Medicare payment can only be made on an assigned basis. That is not the case with diabetic supplies. Thus, we are not eliminating the AOB form for diabetic supplies.

• *DMERC Information Form (DIF).* The DIF is a form created by the DMERC Medical Directors that contains information regarding the dates of the beneficiary's transplant and other diagnosis information. This form is a one-time requirement that pharmacies must complete in order to receive payment. Since section 1861(s)(2)(J) of the Act no longer imposes limits on the period of time for coverage of immunosuppressive drugs, we believe that the information on transplant diagnosis can be captured through other means (for example, diagnosis codes on the Part B claim form).

Comment: Several commenters applauded our efforts to eliminate use of the DIF in an effort to reduce the cost that the billing requirements imposed. These commenters asked that we ensure that this requirement is applied uniformly by all the DMERCs.

Response: We appreciate the support regarding the elimination of the DIF form. Action is being taken to eliminate the DIF form, including accommodating systems issues and providing for notifications. We anticipate resolution of issues to occur soon and elimination would occur next year.

• *Other Billing Issues.* We also received other comments regarding other billing issues related to the supplying of immunosuppressive, oral anti-cancer, and oral anti-emetic drugs.

Comment: Commenters suggested that we allow physicians to bill the carrier when oral drugs are provided directly by the physician in his office rather than having the physician bill the DMERC for the oral anti-cancer drug. Others stated that we should allow for billing for pharmaceutical products to be conducted on current electronic platforms, because ''batch billing'' creates operational and patient care problems, and adds significant participation costs. Commenters also stated that we should eliminate the requirement for a diagnosis code to be present on the prescription; while, at the same time, adopt the usage of the physician's DEA number instead of the UPIN number when submitting claims.

Response: We thank the commenters for identifying these issues. We plan to examine these aspects of billing.

6. Shipping Time Frame

In the proposed rule, we highlighted the fact that the guidelines regarding the time frame for subsequent deliveries of refills of DMEPOS products had been revised. Effective February 2, 2004, the shipping of refills of DMEPOS products may occur ''approximately'' on the 25th day of the month in the case of a month's supply. In the proposed rule, we emphasized the word ''approximately''; while we indicated that normal ground service shipping would allow delivery in 5 days, if there were circumstances where ground service could not occur in 5 days, the guideline would still be met if the shipment occurs in 6 or 7 days. This change should eliminate the need for suppliers to utilize overnight shipping methods and would permit the shipping of drugs via less expensive ground service.

F. Section 952—Revision to Reassignment Provisions

As discussed in the August 5, 2004 proposed rule, section 1842(b)(6)(A)(ii) of the Act, as amended by section 952 of the MMA, allows, in many circumstances, a physician or NPP to reassign payment for Medicare-covered services, regardless of the site of service, providing there is a contractual arrangement between the physician or NPP and the entity through which the entity submits the bill for those services. Thus, the services may be provided on or off the premises of the entity receiving the reassigned payments. The MMA Conference Agreement states that entities that retain independent contractors may enroll in the Medicare program. The expanded exception created by section 952 of the MMA applies to those situations when an entity seeks to obtain the medical services of a physician or NPP.

Section 952 of the MMA states that reassignment is permissible if the contractual arrangement between the entity that submits the bill for the service and the physician or NPP who performs the service meets the program integrity and other safeguards as the Secretary may determine to be appropriate. The Conference Agreement supports appropriate program integrity efforts for entities with independent contractors that bill the Medicare program, including joint and several liability (that is, both the entity accepting reassignment and the physician or NPP providing a service are both liable for any Medicare overpayments). The Conference Agreement also recommends that physicians or NPPs have unrestricted access to the billings submitted on their behalf by entities with which they contract. We incorporated these recommended safeguards in a change to the Medicare Manual, implementing section 952 of the MMA that was published on February 27, 2004. In the August 5, 2004 rule, we proposed to revise § 424.71 and § 424.80 to reflect these safeguards, as well as the expanded exception established by section 952 of the MMA.

Section 952 of the MMA revises only the statutory reassignment exceptions relevant to services provided in facilities and clinics (section 1842(b)(6)(A)(ii) of the Act). Section 952 of the MMA does not alter an individual or entity's obligations under any other applicable Medicare statutes or regulations governing billing or claims submission.

In addition, physician group practices should be mindful that compliance with the physicians' services exception and the in-office ancillary services exception to the physician self-referral prohibition in section 1877 of the Act requires that a physician or NPP who is engaged by a group practice as an independent contractor may provide ''designated health services'' to the group practice's patients only in the group's facilities. See the definition of physician in the group at 42 CFR 411.351.

We also cautioned that parties must be mindful that contractual arrangements involving reassignment may not be used to camouflage inappropriate fee-splitting arrangements

or payments for referrals. In the August 5, 2004 proposed rule, we solicited comments on potential program vulnerabilities and on possible additional program integrity safeguards to guard against those vulnerabilities.

Comment: We received positive comments for the proposed changes to the reassignment rules from two physician associations and one association representing non-physician practitioners.

Response: We are pleased to receive positive feedback to the changes to the reassignment rules. We believe these changes balance the need to respond to the changing business arrangements in the delivery of health care services with the need to protect the Medicare trust funds from fraudulent and abusive billing practices.

Comment: An association representing emergency medicine physicians and numerous members of that association commented that requiring independent contractor physicians to have unrestricted access to the billings submitted on their behalf is not sufficient to ensure such access. The commenters requested that we revise our regulations to require the entity submitting the bills to provide duplicates of the Medicare remittance notices (which indicate the services billed and the amounts paid for those services) to the independent contractor physicians. Some of the commenters requested that we require independent contractor physicians to receive itemized monthly reports of the claims submitted and remittances received on their behalf.

Response: We believe that requiring independent contractors to have unrestricted access to the billings submitted on their behalf is sufficient to satisfy the independent contractors' need to review the claims information.

We recognize that some independent contractors may not wish to receive copies of all bills submitted on their behalf. It would place an unnecessary burden on entities if we require them to furnish duplicate remittance notices to independent contractors on a routine basis. Similarly, it would place a significant burden on our claims processing systems if we were obligated to provide duplicate remittance notices to those who have reassigned their payments. We note that the method and frequency of obtaining access to billing records is an issue that the independent contractor and the entity to which the independent contractor is reassigning payments can resolve in their written contract.

Comment: A commenter asked whether or not the new reassignment exception (which essentially expanded or revised the previous exceptions pertaining to independent contractors), established by section 952 of the MMA, is available when one entity contracts with a second entity, which in turn contracts with a physician or non-physician practitioner to furnish services for the first entity.

Response: We refer to this situation as an indirect contractual arrangement between the independent contractor furnishing the service and the entity doing the billing and receiving payment (excluding billing agents). Thus, the reassignment is between the individual furnishing the service and the entity receiving the reassigned benefits. Indirect contractual arrangements were permissible prior to passage of section 952 of the MMA and remain permissible. The CMS–855–R enrollment form would need to be completed by the entity receiving the reassigned benefits and the person furnishing the service. In accordance with section 952 of the MMA, the contractual arrangement and any program integrity safeguard requirements deemed appropriate by the Secretary are between the independent contractor and the entity receiving the reassigned payments, with the program integrity safeguards applying to both parties. If the parties involved also wish to include the intermediary entity in a similar contract, and apply standards identical or similar to the program integrity safeguards to their arrangement, they have that option; but, it is not required or necessary to comply with the exception to the reassignment prohibition for contractual arrangements.

Comment: Several members of the Congress urged us not to delay the enrollment process of providers or suppliers while implementing section 952 of the MMA.

Response: We do not expect any delays in provider or supplier enrollment to result from implementing the reassignment provisions of this regulation. We are sensitive to the need for an efficient and timely enrollment process. If the new reassignment exception results in the submission of a particularly high volume of claims, or if a Medicare contractor has to process a large number of new enrollment applications, it is possible that delays may occur in some cases. A provider or supplier whose enrollment was delayed must contact the appropriate Medicare contractor's provider or supplier enrollment office to discuss the reasons for the delay.

Comment: A trade association of physician specialists asked that we clarify our definitions of onsite and off-site services. This trade association also requested that we further describe the potential program vulnerabilities that the revised Medicare reassignment exception might create.

Response: We consider onsite services to be services of an independent contractor that are performed in space owned or leased by the entity billing and receiving the reassigned payments. We consider offsite services to be services of an independent contractor that are performed in space that is not owned or leased by the entity billing and receiving the reassigned payments, that is, services performed off the premises.

The Congress originally passed the prohibition on reassignment provision due to experience with fraudulent and abusive billing practices. As we discussed in the preamble to the August 5, 2004 proposed rule, the new reassignment exception for contractual arrangements will potentially permit myriad relationships and financial arrangements. Some of these relationships may have the potential to increase fraudulent and abusive billing practices that the reassignment rules were designed to prevent. We also stated in the proposed rule that the new reassignment exception does not alter an individual's or entity's obligations under existing Medicare statutes and regulations (for example, the physician self-referral prohibition, the anti-kickback statute, purchased diagnostic test rules, incident to rules, etc.).

Comment: Several commenters expressed concern over the recent growth of so-called pod, salon, turnkey, mini-mall, or condo labs, especially since section 952 of the MMA appears to liberalize the Medicare reassignment rules.

As we understand the situation, some entities have created a building or a floor of a building that contains a number of cubicles, each of which is equipped with a microscope and other supplies that enable a pathologist to go to a particular cubicle or pod to analyze any tissue sample that is submitted by the group practice that rents pod space on a full-time basis. Apparently, some of the owners of these anatomical laboratories assert that each pod is a centralized location for a laboratory that is owned by a group practice. Other owners assert that each pod serves as an offsite office of a pathologist who works for a group practice as an independent contractor.

These entities market their services to specialists in certain disciplines, such as gastroenterology, urology, and dermatology, which rely on a high

volume of anatomic pathology services. The commenters stated that these lab arrangements are subject to excess, waste, and abuse, including, but not limited to: (a) Generation of medically unnecessary biopsies; (b) kickbacks; (c) fee-splitting; and, (d) referrals that would otherwise be prohibited under the physician self-referral statute.

The commenters agree with us that safeguards are necessary to prevent the increased incidence of fraudulent and abusive billing practices resulting from the new reassignment exception for contractual arrangements. To reach the goal of closing any loophole for excess, waste, and abuse opened by the new independent contractor reassignment exception, the commenters provided several suggestions. One commenter recommends that we add language to proposed § 424.80(d) that would prohibit a physician from making a reassignment to another physician, under the independent contractor exception, if the physicians do not practice in substantially the same medical specialty. This limitation would not apply if the entity accepting the assignment is a bona fide multi-specialty physician practice, meaning that it employs (on a W–2 basis) physicians who regularly practice in two or more specialties of medicine.

The commenters believe that the regulations need to state more clearly that all requirements of the purchased diagnostic test rules and purchased test interpretation rules need to be met. In other words, the commenters want to prevent the new reassignment exception from applying to services furnished by independent contractor pathologists.

These commenters are urging us to review these practices to see if they fail to meet existing obligations under the physician self-referral prohibition or anti-kickback statute. The commenters believe that these business arrangements are exploiting the in-office ancillary services exception and other exceptions to the physician self-referral prohibition.

Response: We appreciate comments that specify situations where fraud and abuse may occur and propose solutions to prevent such occurrences. While we decline to incorporate the commenters' suggested regulatory revisions at this time, we share the commenters' concerns. We will be paying close attention to this issue, and may initiate future rulemaking to address arrangements that are fraudulent or abusive.

To respond to commenters' concerns, we are amending the regulations governing reassignment at § 424.80(a) to clarify that nothing in § 424.80 alters an individual or entity's obligations under other Medicare statutes or rules, including, but not limited to, the physician self-referral prohibition (section 1877 of the Act), the anti-kickback statute (section 1128(B)(b)(1) of the Act), the regulations regarding purchased diagnostic tests, and regulations regarding services and supplies provided incident to a physician's services.

In response to the concerns expressed by the commenters, we wish to further expand on the fact that section 952 of the MMA did not affect the obligation of an individual or entity to comply with the physician self-referral prohibition (section 1877 of the Act and the corresponding regulations). As stated in the proposed rule, ''physician group practices should be mindful that compliance with the in-office ancillary services exception to the physician self-referral prohibition requires that a physician who is engaged by a group practice on an independent contractor basis must provide services to the group practice's patients in the group's facilities. As noted in the Phase I physician self-referral final rule (66 FR 887), ''we consider an independent contractor physician to be 'in the group practice' if: (1) He or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities; (2) the contract contains compensation terms that are the same as those that apply to group members under section 1877(h)(4)(iv) of the Act or the contract fits in the personal services exception; and, (3) the contract complies with the reassignment rules * * * '' See also 66 FR 886.'' This test is specified at § 411.351 in the definition of physician in the group practice, which contains a premises requirement independent of the reassignment rules.

In addition, the use of independent contractors at off-premises locations may impact the ability of a group practice to meet the definition of a group practice at § 411.352 for purposes of complying with section 1877 of the Act. Accordingly, some group practices may need to be careful about the number of physician-patient encounters that independent contractors perform off-premises to ensure that they meet the 75 percent patient-physician encounters test as set forth in § 411.352(h).

We will continue to monitor compliance with the reassignment rules and we will analyze the impact of the physician self-referral prohibition on ''pod'' labs. If we determine that changes to the physician self-referral prohibition are necessary, these changes will be made in a separate rulemaking document.

Comment: We received a number of comments and recommendations from three organizations that utilize the services of independent contractor emergency department physicians. One of the three organizations represents management companies that employ independent contractor emergency department physicians. The commenters believe that the changes to the reassignment rules necessitated by section 952 of the MMA should be implemented in a manner that does not impose additional burdens on the Medicare enrollment process. They believe that implementation of the proposed regulations could impede the enrollment process. They expressed concern that amendments to current contracts might be necessary to incorporate the program integrity safeguards included in the proposed regulations. Since they believe requiring contract amendments would be burdensome and costly to hospitals, they are urging us not to require parties to amend their contracts to reflect the program integrity safeguards that we proposed.

Response: We do not believe that implementation of the proposed regulations will impede the enrollment process. Our proposed regulations would not require parties to amend their contracts to reflect the program integrity safeguards. We plan to include the program integrity safeguard requirements on the CMS–855–R enrollment form. The program integrity safeguards will apply to arrangements entered into pursuant to the new reassignment exception for contractual arrangements, regardless of whether the parties reference the safeguards in their contracts.

Comment: Three commenters representing groups that utilize independent contractor emergency physicians strongly oppose our implementation of the two proposed program integrity safeguard requirements: (1) Joint and several liability/responsibility for Medicare overpayments; and (2) unrestricted access to the billings for services provided by independent contractors. The commenters believe that establishing program integrity safeguards is premature and that we should first formally assess the need for such safeguards. These commenters also ask us to clearly define joint and several liability/responsibility. They express concern over our attempt to impose joint and several liability/responsibility on both the contracting entity and practitioner furnishing the services and

note that the CMS–855–R enrollment form certification holds the enrolling provider or supplier responsible for any Medicare overpayments. The commenters argue that we should impose these program integrity safeguards on employer/employee relationships if we are going to impose them on contractual arrangements. The commenters ask how we would monitor compliance with joint and several liability/responsibility. The commenters also have concerns about regulating access to claims submitted by an entity for services furnished by an independent contractor. In their view, this type of requirement should be part of the compliance programs of entities and employers rather than mandated as part of the reassignment rules.

Response: We disagree with the commenters' assertion that it is premature to implement the proposed program integrity safeguards. Section 952 of the MMA specifically authorizes the Secretary to implement program integrity safeguards. Further, in the Conference Report to the MMA, the Congress specifically highlighted the two program integrity safeguards that we have proposed.

Our assessment of the need for program integrity safeguards is based upon prior experience with certain types of entities and their subsidiary billing companies. For example, on April 6, 2000, Lewis Morris, Assistant Inspector General for Legal Affairs, Office of Inspector General (OIG), U.S. Department of Health and Human Services, testified before the House Committee on Commerce, Subcommittee on Oversight and Investigations regarding Medicare and third-party billing companies. Mr. Morris of the OIG detailed the upcoding activities of two firms that provided billing services for entities contracting with emergency department physicians. One firm paid $15 million and the other paid $15.5 million to settle their respective liabilities. Moreover, as we have noted, we have received numerous comments from physicians stating that they have been prevented from seeing the Medicare remittance notices for services they furnished, on penalty of termination.

In addition, we understand the commenters' concerns that if the Agency plans to implement the two proposed program integrity safeguards, we should apply these same program integrity safeguards to employees, as well as to independent contractors. Joint and several responsibility/liability and unrestricted access to billings may or may not be appropriate for employees and employers as it is for the parties involved in contractual arrangements. CMS will study this issue further, and if necessary will address it in a separate rulemaking document.

We use the words responsibility and liability interchangeably, and in the context of claims filing and payment, they both have the same meaning. We define joint and several liability/responsibility to mean that both the person furnishing a service and the entity billing for that service (and to which payments have been reassigned) can be held liable or responsible for any errors in billing that result in a Medicare overpayment, including, but not limited to, upcoding and billing for services never rendered.

We will monitor the program integrity safeguards as we monitor all other program integrity requirements. We also believe that entities and independent contractors will report violations to us, since both may be held responsible for any Medicare overpayments. If an independent contractor is refused access to the billings submitted on his or her behalf, the independent contractor may report this to the appropriate Medicare contractor.

Comment: An organization representing entities that use independent contactor emergency department physicians believes if we retain the proposed program integrity requirements, then these requirements should be clarified and included in other reassignment exceptions and in other Medicare conditions of participation.

Response: It is our goal to have the program integrity requirements identified and included on the appropriate CMS–855–R enrollment form. As we have discussed above, while we will study whether it is appropriate to extend the program integrity safeguards to employer/employee relationships, we do not believe it is necessary to include the program integrity requirements in other reassignment exceptions (or in other Medicare conditions of participation) at this time.

Comment: Three commenters representing organizations that use independent contractor emergency physicians recommend that we revise our definition of entity to specifically identify the types of entities that are listed in the Conference Report to section 952 of the MMA. They believe that our existing definition which defines entity as a person, group or facility enrolled in the Medicare program is ambiguous and inconsistent with Congressional intent. Therefore, they are recommending that we add the language to the definition that specifies that an entity includes but is not limited to, a hospital, clinic, medical group, a physician practice management organization, or a staffing company. One of the commenters opposes stating that entities need to be enrolled in Medicare in the definition of entity because the commenter believes it is not necessary to include such information in the regulations on reassignment. This commenter believes that instructions on enrollment should be addressed in an enrollment regulation. The commenter also states that our current reassignment regulation does not define facility as a hospital or other institution enrolled in the Medicare program. These groups believe that their proposed definition of entity more accurately reflects the language from the Statement of the Managers filed by the MMA Conference Committee and is included in the Conference Report (Conference Agreement). Finally, these groups do not believe that a definition of entity is necessary, since we do not define employer in the reassignment regulations definition section.

Response: We continue to believe that our definition of entity in the proposed rule is appropriate. We believe that defining entity as a person, group, or facility that is enrolled in Medicare encompasses all entities that are allowed to bill and receive payment from Medicare, and does not prevent those entities that were specifically identified in the Conference Report from benefiting from the new contractual arrangement reassignment exception. We will not specifically include a staffing company in the definition of entity because a staffing company cannot enroll in Medicare as a staffing company. Staffing companies can enroll as either a group practice or clinic, depending on how they are licensed or allowed to do business in the state where they are located. We further believe that a definition of entity is necessary to distinguish between entities that are allowed to reassign their right to payment and to receive reassigned payments from entities that are not allowed to reassign their right to payment or to receive reassigned payments (for example, billing agents, entities that provide services under arrangements, and substitute physicians, (for example, locum tenens physicians or physicians working on a reciprocal basis) all of which are not required to enroll in Medicare).

Comment: Three commenters representing organizations that use independent contractor emergency physicians found our use of the term supplier confusing when denoting the physician or non-physician practitioner

that contracts with an entity and reassigns his or her right to bill and receive payment. Specifically, the commenters found the proposed revision to § 424.80(c) (Prohibition on reassignment of claims by suppliers) confusing because it refers to a hospital or facility as the supplier of services for purposes of the reassignment revision when Medicare already has regulations that separately define provider and supplier. The commenters recommend that we clarify our intent regarding the use of the term supplier.

Response: In instances of reassignment, the supplier is the person furnishing the service and reassigning his or her right to bill and receive payment to another entity. This is consistent with our definition of supplier in § 400.202. In our proposed revision to § 424.80(c), we state that the employer or entity is considered to be the supplier of the services for subparts C, D, and E of this part, subject to the provisions of paragraph (d) of the section. Once a supplier reassigns his or her right to receive Medicare payments, the entity receiving the reassigned payments essentially takes the place of the supplier. We have revised § 424.80(c) to reflect the new contractual arrangement reassignment exception. The existing § 424.80(c) includes the same formulation and we have simply proposed to replace the words ''facility'' and ''system'' with ''entity,'' because the new exception for payment to an entity under a contractual arrangement now replaces the previous exceptions for payment to a facility or health care delivery system.

Comment: Three commenters that use independent contractor emergency physicians expressed concern about our statement in the preamble to the proposed rule that the new reassignment exception may create fraud and abuse vulnerabilities, which may not become apparent until the program has experience with the range of contractual arrangements permitted by the new reassignment exception. These groups do not believe that the new reassignment exception will result in an increase in violations of the types addressed in the preamble to the proposed rule. The groups also disagree with our statement in the preamble to the proposed rule that contractual arrangements with independent contractor physicians may be used to camouflage inappropriate fee-splitting arrangements or payment for referrals. These groups state that Medicare does not govern fee-splitting arrangements, that policing such arrangements is a matter of State law, and that Medicare reassignment policy has no direct effect on this issue. They question why we have expressed concern over potential violations of the physician self-referral prohibition, because section 952 of the MMA does not affect or otherwise change the obligation of providers and suppliers to comply with the physician self-referral prohibition and its accompanying regulations.

Response: The Congress originally passed the prohibition on reassignment provision because of increasing fraud and abuse in billing practices. Since the new reassignment exception has expanded the circumstances under which suppliers can reassign their right to receive Medicare payments, we are concerned that the potential exists for an increased incidence of fraud and abuse, which may not become apparent until the program has experience with the range of contractual arrangements permitted by the new reassignment exception. Fee-splitting arrangements may violate the physician self-referral prohibition and the anti-kickback statute. Preventing fraudulent and abusive billing practices continues to be the primary purpose of the reassignment rules, even as they are amended to reflect changing practices in the delivery of health care.

We agree that section 952 of the MMA does not change the obligations of providers and suppliers under the physician self-referral prohibition, and all other Medicare statutes and regulations. We are incorporating this clarification in § 424.80(a).

Comment: Three organizations that use independent contractor emergency physicians raised procedural concerns regarding the timing of the final rule, which is effective January 1, 2005. The commenters claim that providers and suppliers do not have time to comply with the new program integrity safeguards. They are asking us to provide providers and suppliers with an additional time frame of at least six months for compliance with the program integrity safeguards, if they are finalized. They recommend that we make the new safeguards applicable to enrollment applications submitted on or after the effective date of the final rule.

Response: We do not believe additional time is necessary for compliance with the program integrity safeguards. Providers and suppliers will not have to amend contracts to include the proposed program integrity requirements. Thus, enrollment applications are not affected by this regulation. The program integrity safeguards will be effective on the effective date of this final rule and these requirements will be applicable to all Medicare providers and suppliers affected by the section 952 change to the reassignment rules.

Comment: One commenter believes that the public comment period for this rule was shortened to 50 days instead of the 60-day comment period required by statute. The proposed rule was published in the **Federal Register** on August 5, 2004 and the public comment period ended at 5 p.m. on September 24, 2004.

Response: While the law requires that we provide a 60-day public comment period and that the notice of proposed rulemaking be published in the **Federal Register**, it does not require that the date of **Federal Register** publication be the first day of the comment period. The two requirements are independent. We post the proposed rule on our Web site on the date of display of the proposed rule at the Office of the Federal Register, satisfying the requirement for a 60-day comment period. By making the proposed rule available on the CMS Web site (as well as at the Office of the Federal Register), we provided the public with access to not only the proposed rule, but also to all of the supporting files and documents cited in the proposed rule in a manner that can be used for analysis. We note that the computer files posted on the Web site can be used for independent analysis. Therefore, we believe that beginning the comment period for the proposed rule with the display date at the Office of the Federal Register, and posting the proposed rule and data files on the CMS Web site on the display date, fully complies with the statute and provides a far better opportunity for the public to have meaningful input than the past practice under which the comment period began with the publication date in the **Federal Register**, a week or longer after the display date and no other data in any other form was furnished.

G. Section 642—Extension of Coverage of IVIG for the Treatment of Primary Immune Deficiency Diseases in the Home

In the August 5, 2004 proposed rule, we stated that for dates of service beginning on or after January 1, 2004, Medicare would pay for IVIG administered in the home. The benefit is for the drug and not for the items or services related to the administration of the drug when administered in the home, if deemed medically appropriate. The implementing instructions for this benefit were provided in a transmittal released on January 23, 2004. We received several comments regarding this new benefit. The comments and our responses are provided below.

Comment: Several commenters expressed concern regarding the lack of coverage for the items and services needed to administer IVIG. These commenters urged us to use our authority to pay for the items that are necessary for the effective use of IVIG.

Response: The MMA provided coverage for the approved pool plasma derivative for treatment in the home; however, new section 1861(zz) of the Act specifically precludes coverage for the items and services related to the administration of the derivative.

Comment: The commenter stated that on January 23, 2004, we released a transmittal implementing the new IVIG coverage. The transmittal contained the following language: ''for coverage of IVIG under this benefit, it is not necessary for the derivative (IVIG) to be administered through a piece of durable medical equipment.'' Commenters stated that this language has resulted in the denial of coverage of IVIG for patients because providers are using the rationale that it is medically unnecessary to infuse IVIG through an infusion pump and therefore IVIG is medically unnecessary. The commenters recommended that we issue a new transmittal stating that IVIG is to be covered even when administered through durable medical equipment (DME), as determined necessary by a physician.

Response: It was not our intention to deny any beneficiary the coverage of IVIG in the home. It appears that the sentence that references the use of DME for the administration of IVIG is both confusing and misleading. Therefore, we will issue a new transmittal removing the apparent DME restriction.

Result of Evaluation of Comments

We are finalizing the proposed revisions to § 410.10 without alteration.

H. Section 623—Payment for Renal Dialysis Services

Section 623 of the MMA amended section 1881(b) of the Act and directed the Secretary to revise the current renal dialysis composite rate payment system. The MMA included several major provisions that require the development of revised composite payment rates for ESRD facilities.

The following is a summary of the proposed revisions to the composite payments rate methodology implementing provisions in section 623 of the MMA that are required to be effective January 1, 2005.

- The proposed rule provides for a 1.6 percent increase to the current composite payment rates effective January 1, 2005.
- The proposed rule included an add-on to the composite rate for the difference between current payments for separately billable drugs and payments based on a revised drug pricing methodology using acquisition costs. For purposes of this adjustment, in the proposed rule, we defined acquisition costs as the ASP minus 3 percent. We proposed a single adjustment to the composite payment rates for both hospital-based and independent facilities, equal to 11.3 percent.
- In the proposed rule, we discussed the reinstatement of the ESRD exceptions process for pediatric facilities as provided in section 623(b) of MMA. The statute defines pediatric ESRD facilities as renal facilities at least 50 percent of whose patients are under age 18. Since April 1, 2004, we have accepted ESRD composite rate exception requests from ESRD facilities that believe they qualify for exceptions as pediatric ESRD facilities.
- Section 1881(b)(12)(D) of the Act, added by section 623(d)(1) of the MMA gives the Secretary discretionary authority to revise the current wage indexes and the urban and rural definitions used to develop them. In the proposed rule, we proposed to take no action at this time to revise the current composite rate wage indexes. Because of the potential payment implications of recently revised definitions of urban areas, we believe further study is required.
- The proposed rule described the proposed methodology for a case-mix adjustment to a facility's composite payment rate based on the statutorily required limited number of patient characteristics. We used co-morbidity data for all Medicare ESRD patients obtained from the Form CMS–2728, supplemented with co-morbidity information obtained from Medicare claims. We measured the degree of the relationship between specified co-morbidities and ESRD facility per treatment costs, controlling for the effects of other variables, using standard least square regression. The source of the per treatment costs was the Medicare cost report. The result, after all necessary statistical adjustments, was a set of eight case-mix adjustment factors based on age, gender, AIDS, and peripheral vascular disease (PVD). Section 623(d)(1) of the MMA requires that aggregate payments under the case-mix adjusted composite payment system be budget neutral. Therefore, the proposed rule provided an adjustment 0.8390 to be applied to a facility's composite payment rate to account for the effects of the case-mix adjustments.

A. Composite Rate Increase

The current composite payment rates applicable to urban and rural hospital-based and independent ESRD facilities were effective January 1, 2002. Section 623(a)(3) of the MMA requires that the composite rates in effect on December 31, 2004 be increased by 1.6 percent. The updated wage adjusted rates were published in Tables 18 and 19 of the proposed notice.

The tables reflected the updated hospital-based and independent facility composite rate of $132.41 and $128.35, respectively, adjusted by the current wage index. The rates shown in the tables do not include any of the basic case-mix adjustments required under section 623 of the MMA.

Comment: Although there were no specific comments on the 1.6 percent adjustment, several commenters wanted to emphasize the importance of providing an annual adjustment to the composite rate in order to recognize the increased costs that face renal dialysis facilities. They stated that failure to increase the composite rate on a regular basis has caused dialysis providers to suffer a significant loss of income from their Medicare reimbursement and that dialysis facilities are the only Medicare entities that do not receive a statutorily mandated annual increase in their reimbursement rates.

Response: We do not have the authority to establish an annual update to the composite payment rates. Section 4201(a)(2) of Pub. L. 101–508 effectively froze the methodology for calculation of the rates, including the data and definitions used as of January 1, 1991. Since that time, the Congress has set the composite payment rate for ESRD services furnished to Medicare beneficiaries. As a result, we do not have the authority to update the composite payment rate.

B. Composite Rate Adjustments To Account for Changes in Pricing of Separately Billable Drugs and Biologicals

Section 623(d) of MMA provides for an add-on to the composite rate for thedifference between current payments for separately billable drugs and payments based on a revised drug pricing methodology using acquisition costs.

In the proposed notice we proposed to pay for separately billable ESRD drugs using ASP minus 3 percent based on the average relationship of acquisition costs to average sales prices from the drug manufacturers as outlined in the OIG report. We developed the proposed drug add-on adjustment using the ASP minus

3 percent drug prices. As discussed below, the drug add-on adjustment for this final rule is based on average acquisition costs for the top ten ESRD drugs updated to 2005 and ASP plus 6 percent for the remaining separately billable ESRD drugs. *See* section III.E, Payment for Covered Outpatient Drugs and Biologicals, for a discussion of the final payment methodology for ESRD separately billable drugs.

In the proposed notice, we outlined the methodology and data used to develop the proposed drug add-on adjustment to the composite rate of 11.3 percent for both hospital-based and independent ESRD facilities. Since the composite rate payment for hospital-based facilities is higher than the composite rate for independent facilities, the proposed adjustment results in a higher payment rate for hospital-based facilities. The 2005 composite rates (including the 1.6 percent increase) would be $132.41 for hospital-based facilities and $128.35 for independent facilities with the hospital-based facilities' rate higher by $4.06. We found this result consistent with section 1881(b)(7) of the Act, which requires that our payment methods differentiate between hospital-based facilities and others. We also indicated that the proposed methodology for making this drug add-on adjustment to the composite rate is designed to ensure that the aggregate payments to ESRD facilities for separately billable drugs would be budget neutral with what would have been paid absent the MMA provisions.

The proposed rule also discussed an alternative approach that produced separate adjustments to the composite rate of 2.7 percent for hospital-based and 12.8 percent for independent facilities. In contrast to a single add-on, separate add-on adjustments would result in a significantly higher composite payment rate for independent facilities than hospital-based facilities, of $8.79 more per treatment.

Comment: We received many comments from independent facilities, chain organizations and groups objecting to our proposal to establish a single add-on adjustment to the composite payment rate. Several commenters expressed concern that since hospital-based facilities are paid reasonable cost for their separately billed drugs other than EPO, those facilities should receive an adjustment based only on the spread related to EPO payments. They stated that our proposal to spread the drug savings to all facilities does not comply with the provision in the statute that they believe is intended to hold facilities harmless with respect to their drug payment profit margins. The commenters also contend that since hospital-based facilities already receive about $4.00 per treatment more than independent facilities, they should not share in the drug add-on adjustment for other than their specific EPO usage.

Response: As we indicated in the proposed rule, we believe that the statutory language supports one uniform drug add-on adjustment to composite payment rates set forth in section 1881(b)(7) of the Act after updating by 1.6 percent. The provision speaks of one ''difference between payment amounts'' and ''acquisition costs * * * as determined by the Inspector General.'' It is reasonable to infer that the Congress intended us to compute one ''difference'' based only on the payment amounts under sections 1842(o) and 1881(b)(11) of the Act.

Although the language of section 1881(b)(7) contemplates differential composite rates for hospital-based facilities and 623(d) contemplates existing composite rates as the starting point for application of the new rate adjustments prescribed under section 1881(b)(12)(A) of the Act, the MMA language does not suggest that these adjustments would be applied differentially across facilities. Otherwise, all of the adjustments, including case-mix and budget neutrality would have to be developed separately based on facility type.

We note that the amount of the drug add-on has decreased significantly from the proposed rule as a result of our revised policy of paying for ESRD drugs for 2005. Since the drug payment amounts increased, the amount of the drug add-on to the composite rate decreased. The resulting drug add-on amount is now 8.7 percent.

We also note that there is not a significant difference in composite rates for independent facilities under single and separate add-ons. With a single add-on of 8.7 percent, the 2005 composite rate for independent facilities would be $139.52. Under a separate add-on approach, the 2005 composite rate for independent facilities would be $140.93, a difference of $1.41 or about 1 percent before taking other considerations into account. This difference is about 27 percent less than the difference based on the approach and figures in the proposed rule.

While a composite rate difference of $1.41 is important, such difference does not take into account two other factors: (1) Since Medicare's 2005 payments for ESRD drugs will be a weighted average of the acquisition costs determined by the Inspector General, the payment amounts for the most utilized ESRD drugs (such as EPO) will be significantly higher than payment based on ASP–3 percent; and (2) Beginning with 2005, Medicare will pay separately for syringes that are currently included in the EPO payments.

With separate add-ons, the composite rate for the independent facilities would be $7.33 higher than the composite rate for hospital-based facilities. However, the composite rate for hospital-based facilities would be $10.33 lower under separate add-ons than under a single add-on approach. We believe the current difference in composite rates where the hospital-based rate is about $4.00 higher than the independent facility rate would effectively be preserved with a single add-on and significantly reversed with separate add-ons.

Finally, we note that a key purpose of the MMA legislation was to eliminate the cross-subsidization of composite rate payments by drug payments. If the composite rate was inadequate before the MMA provision, it was inadequate for both hospital-based and independent facilities. As such, increasing the composite rate by relatively greater amounts for independent facilities than hospital-based facilities would place the latter facilities at a competitive disadvantage relative to the former facilities.

Comment: One comment from a drug manufacturer suggested that in order to preserve high quality care to ESRD patients and prevent cost shifting behavior, we should require a facility to provide the full range of separately reimbursable drugs and biologicals in order to receive the drug add-on adjustment.

Response: We do not believe the statute permits imposing such a requirement as a condition for receiving the add-on adjustment to the composite rate. However, other regulations require that ESRD facilities provide appropriate care to each patient based on a plan of care that would include the administration of medically necessary drugs as prescribed by the patient's dialysis physician.

1. Growth Factors Used To Update Drug Expenditures and Prices

Comment: One commenter noted that, in the proposed rule, we updated the 2004 ASP drug prices to 2005 prices by using the projected annual growth factor for National Health Expenditures prescription drugs of 3.39 percent. This commenter wanted to know why we did not use the actual growth factors for separately billable drugs that are furnished by ESRD facilities to ESRD

patients. The commenter states that this factor is currently running about 39 percent.

Response: After consideration of the available price data, as discussed in the section on payment for ESRD separately billable drugs, we have determined that the Producer Price Index (PPI) for prescription preparations is the most appropriate price measure for updating EPO and other separately billable drugs from 2003 to 2005. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) for prescription drugs reflects price changes at the retail stage. Because EPO and many of the separately billable drugs used by dialysis facilities are purchased directly from the manufacturer, the use of a price index that measures wholesale rather than retail prices is more appropriate. The PPI for prescription drugs is the measure used in the various market baskets that update Medicare payments to hospitals, physicians, and skilled nursing facilities, and home health agencies. In addition, the PPI for prescription drugs was recommended for use in the proposed composite rate market basket detailed in the 2003 Report to the Congress.

Based on historical data through the second quarter of 2004, we used the Global Insight Inc. forecast of the PPI for prescription drugs to determine the update factors for 2004 and 2005. We feel the use of an independent forecast, in this case from Global Insight Inc., is superior to using the NHE projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases for Medicare prospective payment systems.

Comment: One comment questioned the 3 percent growth rate that we used in the proposed rule to estimate 2005 Medicare AWP payment amounts for purposes of calculating the drug add-on amount. Specifically, the commenter asked whether the 3 percent figure represented the AWP growth trends for all drugs as opposed to the AWP growth trends for only ESRD separately billable drugs and biologicals. The commenter also asked for clarification of the timeframe used to establish the historical trend.

Several comments also expressed concern that we used a 10-quarter average as an approximation for 2002 expenditures, and as a result, the projected 2005 drug expenditures were understated. These comments strongly recommended that we establish an accurate baseline using actual 2002 expenditures. A study performed for commenters by an industry consultant was cited as confirming that our base year estimate is materially below actual drug spending computed using CMS's 2002 Outpatient Five Percent Standard Analytic File (SAF). Commenters were also concerned that the drug add-on does not reflect the true difference between payments under the current system and acquisition costs described by the OIG.

Response: We have taken all these comments into consideration and have re-evaluated our 2005 projection of aggregate ESRD facility drug expenditures. We did not use an average over 10 quarters to determine aggregate drug payments. The 10 quarters of data were used only to establish historical growth trends. However, we determined that our estimates of aggregate drug payment amounts were in fact understated because they did not include deductibles and coinsurance. Since drug payment rates are set at 100 percent of the allowable payment, we incorrectly calculated the aggregate drug payment for 2005. We revised our calculation to ensure that we capture the allowable payment before deductible and coinsurance are removed. In addition, we updated our estimates to incorporate the June 2004 update to the 2003 standard analytical file. The 3 percent growth represents our best estimate of the expected growth rate in AWP prices. In addition, due to numerous coding changes for the various ESRD drugs, we were unable to do direct comparisons for each of the AWP prices from year-to-year. Therefore, we believe the 3 percent inflation factor we used to update the AWP prices is appropriate.

Comment: One comment expressed concern that the projected number of dialysis treatments in 2005 would be overstated if home peritoneal dialysis (PD) treatments for home patients are included because facilities do not bill for non-EPO drugs in that setting.

Response: Since ESRD facilities also receive composite rate payments for their Method I home patients, the drug add-on would also apply to composite rate payments for those patients. Therefore, it is appropriate for us to count those treatments in projecting the number of dialysis treatments for computation of the drug add-on amount. We did not, however, count treatments attributable to Method II home patients since payment for these patients is made based on reasonable charges as opposed to the composite rate.

Comment: One comment from a patient organization raised concern that the add-on provision would remove any incentives the current payment policy creates for facilities to provide separately billable drugs and biologicals to dialysis patients. This comment suggested that we establish new clinical guidelines or indicators to ensure that dialysis patients receive necessary drugs and biologicals. This commenter also asked whether we have longer term plans to revise payment for dialysis treatment and ancillary services.

Response: We share this commenters concern that changes in payments to dialysis facilities could produce perverse incentives for dialysis facilities to skimp on care to ESRD patients. In order to ensure that patients continue to receive quality care, we are revising the ESRD facility conditions for coverage so that they are more patient-centered and outcome-oriented. We will publish proposed ESRD conditions by the end of 2004. We note that section 623 of MMA also requires us to develop a bundled, case-mix adjusted payment system and report to the Congress by October 1, 2005. This section also requires the establishment of a demonstration to test the revised payment system over a 3-year period beginning January 1, 2006.

2. Update Methodology for Drug Add-on Adjustment in 2006

Comment: Several commenters recommended that we publish the methodology that we intend to use to update the drug add-on component of the basic case-mix adjusted payment amounts, beginning in 2006, and that we provide the opportunity for public comment.

Response: We did not propose a mechanism for updating the 2006 payments in this document since this rule addresses payment for 2005. It is our intent to publish a proposed rule in mid-2005 to address payment changes for 2006. The public will be given an opportunity to comment on those proposals at that time.

3. Computation of Final Drug Add-On Adjustment to the Composite Payment Rate

To develop the final drug add-on adjustment we used historical total aggregate payments for separately billed ESRD drugs for half of 2000 and all of 2001, 2002 and 2003. For EPO, these payments were broken down according to type of ESRD facility (hospital-based versus independent). We also used the 2003 data on dialysis treatments performed by these two types of facilities over the same period.

I. 2005 Average Acquisition Payment (AAP) Amounts

The OIG report contained 2003 average acquisition costs for the top ten drugs supplied by the four largest dialysis chain organizations and by a sample of those facilities not managed by the four largest chain organizations. According to the OIG report, these ten drugs accounted for about 98 percent of total expenditures for separately billed drugs furnished by ESRD facilities. The report also indicated that payment to the four largest dialysis chains accounted for 73 percent of Medicare drug reimbursement in 2002. Therefore, we weighted the average acquisition costs using a 73–27 split. As discussed earlier, we then updated the 2003 weighted average acquisition costs to arrive at the 2005 AAP amounts by using the PPI for prescription drugs. These factors were 4.81 percent and 3.72 percent for 2004 and 2005, respectively.

TABLE 9:

	2003 Average Acquisition Costs	2005 Average Acquisition Payment Amounts
Epogen	$8.98	$9.76
Calcitriol	0.88	0.96
Doxercalciferol	2.39	2.60
Iron dextran	10.07	10.94
Iron sucrose	0.34	0.37
Levocarnitine	12.53	13.63
Paricalcitol	3.68	4.00
Sodium ferric glut	4.55	4.95
Alteplase, Recombinant	29.19	31.74
Vancomycin	2.74	2.98

II. Estimated 2005 Medicare Payment Amounts Based on 95 Percent of AWP

We estimated what Medicare would pay for ESRD drugs in 2005 if the MMA had not been enacted. We adjusted the first quarter 2004 Medicare payment amounts (95 percent of AWP), based on the prices from the January 2004 Single Drug Pricer, for drugs other than EPO, to estimate 2005 prices by using an estimated AWP growth of 3 percent. As discussed earlier, these growth factors are based on historical trends of AWP pricing over years. We did not increase the price for Epogen since payment was maintained at $10.00 per thousand units prior to MMA.

TABLE 10:

Drugs	Estimated 2005 Pre-MMA Medicare Payment Amounts
Epogen	$10.00
Calcitriol	1.42
Doxercalciferol	5.67
Iron dextran	18.45
Iron sucrose	0.68
Levocarnitine	35.23
Paricalcitol	5.49
Sodium ferric glut	8.42
Alteplase, Recombinant	37.80
Vancomycin	7.24

III. Dialysis Treatments

We updated the number of dialysis treatments based on 2003 data by actuarial projected growth in the number of ESRD beneficiaries. Since Medicare covers a maximum of three treatments per week, utilization growth is limited, and therefore any increase in the number of treatments will be due to enrollment. In 2005, we project there will be a total of 34.8 million treatments performed.

IV. Estimated Drug Spending

We updated the total aggregate 2003 Epogen drug spending for hospital-based and independent facilities using historical trend factors. For 2004 and 2005, we increased the 2003 spending levels by trend factors of 1.0 percent for hospital-based facilities and by 10.0 percent for independent facilities based on historical growth from 2000 to 2003.

We also updated the aggregate AWP based spending for separately billed drugs, other than EPO, for independent facilities by using the 10 percent growth factor for Epogen. Since aggregate spending in this category show extremely varied growth in recent history, we could not establish a clear growth trend. For this reason we decided to apply the Epogen growth rate to the other separately billed drugs. Given the problems establishing growth trends for the other drugs, plus the fact the expenditures for Epogen account for about 70 percent of the total spending for the top ten ESRD drugs, we believe this approach to updating all of the separately billed drugs is appropriate.

Additionally, we deducted 50 cents for each administration of Epogen from the total Epogen spending for both hospital based and independent facilities, to account for payment for syringes that is currently included in the EPO payments. Payment for syringes used in administering EPO will be made separately beginning January 1, 2005. In 2005, we estimate that the total spending for syringes associated with the administration of Epogen will amount to $1.6 million for hospital-based facilities and $27 million for independent facilities. For 2005, we estimate that the total spending for Epogen provided in hospital-based facilities will be $210 million, and $2.913 billion for drugs provided in independent facilities ($2.003 billion for Epogen and $910 million for other drugs).

V. Add-On Calculation and Budget Neutrality

For each of the ten drugs in the previous tables, we calculated the percent by which 2005 AAP amounts are projected to be different from the payment amounts under the pre-MMA system. For Epogen, this amount is 2 percent. We applied this 2 percent figure to the total aggregate drug payments for Epogen in hospital-based facilities, resulting in a difference of $5 million.

Since the top 10 ESRD drugs will be paid at 2005 AAP amounts and the remainder will be paid at ASP plus six percent, we then calculated a weighted average of the percentages by which AAP amounts would be below current Medicare prices, for the top 10 drugs, and the percentage by which ASP plus 6 percent would be below current Medicare payment amounts. For other than the top ten drugs, we do not have detailed data on expenditures for drugs billed by ESRD facilities. Therefore, we computed the percentage by which ASP plus 6 percent is below the estimated 2005 pre-MMA payment amounts for those drugs, using the average of the comparable ASP prices for the top 10 ESRD drugs. This procedure resulted in a weighted average of 13 percent by which the overall revised 2005 drug payment amounts applicable to independent facilities is projected to be less than the 2005 estimated pre-MMA system (that is, 95 percent of AWP). We then applied the 13 percent weighted average to total aggregate drug spending projections for independent facilities, producing a projected difference of $385 million.

Combining the 2005 estimates of $5 million and $385 million, for a total of $390 million and then distributing this over a total projected 34.8 million treatments would result in an add-on to the per treatment composite rate of 8.7 percent. We estimate that an 8.7 percent adjustment to the ESRD composite payment rate would be needed to achieve budget neutrality with respect to drug expenditures for ESRD facilities.

A. Patient Characteristic Adjustments

As explained in the proposed rule, the current ESRD composite payment rates are not adjusted for variation in patient characteristics or case-mix. Section 623(d)(1) of the MMA added section 1881(b)(12)(A) of the Act to require that the outpatient dialysis services included in the composite rate be case-mix adjusted. Specifically, the statute requires us to establish a basic case-mix adjusted prospective payment system for dialysis services. Also, the statute requires adjustments under this system for a limited number of patient characteristics. In the proposed notice, we described the development of the methodology for the proposed patient characteristic case-mix adjusters required under the MMA.

In summary, we proposed to use a limited number of patient characteristics that explain variation in reported costs for composite rate services, consistent with the legislative requirement. The proposed adjustment factors are as follows:

TABLE 11:

	Age	Adjustment factor
Female	<65 years	1.11
	65-79 years	1.00
	>79 years	1.16
Male	<65 years	1.21
	65-79 years	1.17
	>79 years	1.23
AIDS		1.15
PVD		1.07

Although the magnitude of some of the patient-specific case-mix adjustments appears to be significant, facility level variation in case-mix is limited because of the overall similarity of the distribution of patients among the eight case-mix classification categories across facility classification groups.

We received a significant number of comments regarding the case-mix adjustment factors, which are summarized in this section with our corresponding responses.

1. Sample Data Used To Develop the Basic Case-Mix System

Comment: Comments regarding the sample or universe used to derive the proposed basic case-mix adjustments in the proposed rule expressed concerns about the size of the sample, the number of hospitals and freestanding facilities included, as well as the number of facilities excluded from the data.

Response: We used the database established by our contractor to develop the basic case-mix system in the proposed rule. Facility cost report data were matched to the corresponding facility billing data to insure that the sample reflected the most valid and reliable data available. The specific methodology used to develop the database is discussed in Kidney Epidemiology and Cost Center's (KECC's) Phase I report. The Phase I report entitled: ''An Expanded Medicare Outpatient End Stage Renal Disease PPS—Phase I'' is available on the University of Michigan Web site: *http://www.sph.umich.edu/kecc.* The contractor has been updating the data files for subsequent phases of their research and is beginning to analyze these data for the bundled prospective payment system. The data used for the basic case-mix proposed system were also assessed in terms of consistency. Data from 2000, 2001, and 2002 were examined separately as well as combined to determine if there were consistent trends over the 3-year period. The data were updated to include the latest 2002 data that was available as of September 2004. The updated data reflect an increase of approximately 10 percent in the number of facilities represented in the database.

Comment: Several comments expressed concerns regarding the timeliness of the data used to develop the proposed case-mix measures. These concerns focused on the availability of cost reports for 2002. In the proposed notice we acknowledged we were delayed in obtaining cost reports for 2002 and that the final rule would reflect the most recent data on the number of cost reports available.

Response: Table 12 indicates the number of dialysis facilities with at least one cost report for 2000 to 2002. This table also reflects the availability of the most recent cost reports data for 2002 and reflects an increase from the proposed rule of an additional 564 cost reports for the independent facilities in 2002.

TABLE 12:

	2000	2001	2002
Independent Facilities	3034	3067	3072
Hospital-based Facilities	476	470	456

The availability of cost reporting data may be delayed because of a number of factors including late submissions by facilities and necessary reconciliation and verification of data by fiscal intermediaries prior to submission to our data systems. The comment on delays and availability of data is also related to concerns expressed by other comments regarding the reporting of co-morbid conditions. Several comments addressed potential inconsistencies in

facility reporting of co-morbid conditions, specifically with the impact of the variation of the reporting of AIDs noted in the 2000 data compared to other years. This variation, coupled with the potential incompleteness of the 2002 data, led us to examine options for selecting the time period to be used for determining the case-mix adjustments.

In this final rule, we have decided to use combined data for the 3-year period 2000–2002, to determine the case-mix adjustment factors. The use of combined data enables us to eliminate any impact caused by annual variation in reporting, delays in the availability of administrative files, and overemphasizing the predictive significance of selected variables, because case-mix variables are combined and averaged over a 3-year period, thus representing a more stable database.

Comment: Several comments focused on the number of facilities that were excluded from the study sample in the development of the proposed case-mix adjustments. For the proposed regulation, we excluded from our sample facilities where cost report data could not be matched to claims data and vice versa, or where key data elements were missing. In addition we excluded outlier facilities (those with high or low average costs, or high or low proportions of co-morbid conditions.) Data from small facilities (fewer than 20 patients) and those with existing composite rate exceptions were also excluded.

Response: We concurred with the recommendation to reassess the sample. For the final rule, we are including, within the sample, data for facilities with existing exceptions. However, we have continued to exclude data for small facilities, outliers, and facilities with missing or unusable data. Missing data excluded approximately 11 percent of the sample, and not including small facilities or outlier facilities eliminated approximately 9 percent of the study sample.

We did not accept the suggestion that smaller sized facilities were proxies for rural facilities, however, and we will continue to study the rural and urban issue in future research and in updates to the wage index.

Overall, including those facilities with exceptions provides a more robust study sample. In this way any effects on the case-mix values due to fluctuations in the data from year to year are greatly diminished.

Comment: Several commenters objected that the database used to develop the basic case mix was not available. One commenter indicated that not having the data made it difficult to evaluate the impact of the proposed case-mix variables on specific facilities.

Response: The database developed for the basic case-mix system is the same database that was developed by the University of Michigan for the ongoing research project to develop a bundled payment system. This database was compiled using our administrative data. We make available for purchase data available in the form of public use files or standard analytic files. Commenters can use the same data files that were used by the University of Michigan to develop the database used. The proposed rule provides the factors necessary to determine impact on individual facilities based on the case-mix within that facility. In addition, we have expanded our discussion of the impact of the case-mix adjustments and have provided a more detailed example to assist facilities in evaluating the impact of the case mix on their specific facilities.

2. Including Co-Morbid Conditions in the Case-Mix Adjustment

Comment: A number of comments expressed concerns regarding the coding of co-morbid conditions. Some comments acknowledged that limited time has been spent by ESRD facilities in coding multiple conditions. Some stressed that training should be provided to ensure that facilities understand this reporting requirement. One commenter attributed the proposed delay in implementation of the case-mix adjustments to potential difficulties in coding co-morbid conditions and in integrating these coded conditions into the payment.

Response: We considered the commenters concerns regarding incorporating co-morbid conditions and the findings from analyzing more recent data. Although our regression modeling suggests that the inclusion of co-morbidities in the case-mix system would be appropriate, we are concerned that the data available to determine patient level co-morbidities may not accurately reflect diagnoses relevant to the dialysis patient population. Therefore, in this final rule we are not including co-morbidities as case-mix adjustments. As discussed later in this section, we are establishing the case-mix adjustments based on the following variables: age, body mass index (BMI) and body surface area (BSA). More recent analysis of the data and clinical concerns expressed regarding the inclusion of AIDs and selected PVD diagnoses support this decision. However, while co-morbid conditions are not currently part of the basic case-mix system, we encourage all facilities to more thoroughly report and code co-morbid conditions on their claims. This will enable appropriate refinements to the basic case-mix adjustments and also provide a better database from which we can develop case-mix measures for a bundled payment system.

Comment: One commenter representing a chain of ESRD facilities stated that we overstated the prevalence of patients with peripheral vascular disease (PVD). The commenter maintained that overstating the incidence of PVD in the ESRD outpatient population results in an overstatement of the offset for budget neutrality because of the proposed 1.07 case-mix adjuster for PVD patients, thereby decreasing the otherwise applicable composite payment rate prior to case-mix adjustments. The commenter identified 51 diagnoses from the list of PVD diagnosis codes included in the proposed rule that he believed were either not reflective of PVD in ESRD patients, were not usually considered as a cause of PVD in ESRD patients, or were poorly differentiated clinically and could occur even in the absence of PVD. The commenter believed that these 51 diagnoses should be excluded from our list of PVD diagnoses for purposes of determining the case-mix and budget neutrality adjustments to the composite payment rates. Another commenter pointed out that there is substantial clinical disagreement about the definition of PVD and that the ESRD claims data presently do not contain sufficient information to implement the proposed PVD adjustor.

Response: The selection of specific co-morbid conditions for purposes of adjusting the composite payment rates to reflect the patient characteristics associated with cost differences across facilities is an important issue, and we appreciate the commenter's suggestions. However, we disagree with the recommendation that we exclude certain diagnoses because they are not usually considered a cause of ESRD in patients. We believe that whether a particular co-morbid condition caused the onset of ESRD is irrelevant. The important factor is whether a particular co-morbid condition is associated with facility differences in composite rate costs, regardless of their role in the etiology of ESRD.

We agree with the commenter's suggestion that diagnoses which can occur in the absence of PVD will be excluded for purposes of applying a case mix adjustment based on PVD. In addition, there is apparent disagreement among clinicians as to whether certain

diagnoses are reflective of PVD in ESRD patients, and we will try to achieve as much consensus as possible before proceeding to implement a case mix adjuster which purports to reflect PVD. Accordingly, we are eliminating the case mix adjustment for PVD as set forth in the proposed rule. We point out that further analyses with more restricted sets of diagnostic codes revealed that the omitted codes were still strong predictors of costs. We intend to revisit the issue of appropriate co-morbidity adjustments as we continue our research to develop the bundled ESRD payment system.

We point out that our case mix model that included PVD explained about 35.7 percent of the variation in facility composite rate costs. By comparison, our model using five age groups without co-morbidities explains about 35.6 percent of the cost variations. Although PVD was a statistically significant case mix variable, its contribution to the model's performance overall in explaining facility differences in costs was minimal. While co-morbidity adjustments will be excluded under the basic case mix adjusted composite payment system, accuracy in the reporting of co-morbid conditions on the bills will become increasingly important because of the likelihood that a bundled ESRD payment system will include co-morbidities associated with differences in patient resource consumption.

Comment: Two commenters recommended that we exclude AIDS as a co-morbidity warranting case-mix adjustment. These commenters stated that because of State laws requiring that a patient's AIDS status be kept confidential, most facilities do not know whether their patients have AIDS. This does not pose a risk to other patients or caregivers because of the universal precautions which dialysis facilities are required to use in order to prevent exposure and infection.

Response: Because the claims data contain primarily the patient's primary diagnosis, AIDS is not likely to be recorded as a claims diagnosis for outpatient dialysis patients. Requiring the recording of the AIDS diagnosis on the bills would create powerful incentives for ESRD facilities to circumvent confidentiality restrictions. In those States with AIDS confidentiality requirements, the diagnosis is not likely to be recorded at all. Given the relatively low incidence of AIDS patients in the outpatient dialysis population, the fact that facilities in States with AIDS confidentiality requirements would be potentially disadvantaged if AIDS were included as a payment adjuster, and the fact that the relationship between AIDS and dialysis costs was not stable from year to year, we have decided to eliminate AIDS as a basis for case-mix adjustment to the composite payment rates at the present time.

3. Case-Mix Adjustment for Gender

Comment: One commenter suggested that we eliminate gender as one of the patient characteristic variables used to case-mix adjust the composite payment rates. The commenter stated that gender was essentially a surrogate for differences in height and weight measures that would yield a superior case-mix adjustment.

Response: Although height and weight are much better predictors of facility variation in composite rate costs, these data were only available on the Form CMS 2728, not on the bills submitted for payment. Accordingly, we used gender as a surrogate measure in proposing adjustments, because gender is reported on the outpatient bill (for example, UB92 or the equivalent electronic form). However, the National Uniform Billing Committee has approved the use of two new value codes for reporting weight and height (A8—weight in kilograms, A9—height in centimeters) on the billing forms effective January 1, 2005.

The mandatory reporting of height and weight permits the development of case mix measures that reflect both variables, such as BMI and BSA, each of which are superior to weight alone as predictors of resource use. Given the impending availability of height and weight data on the outpatient dialysis bill, we examined the predictive power of weight, BMI, and BSA in lieu of gender based on data reported on the Form 2728 from 2000 through 2002. We found that both BMI and BSA are superior predictors to weight alone and that BSA, coupled with a variable for low BMI, is the best predictor of facility differences in composite rate costs. Accordingly, we have eliminated gender in this final rule as a patient classification variable for purposes of case mix adjustment. Instead we are substituting BSA, and a variable for low BMI, each of which are explained in another section of this final rule.

4. Age Groupings Used in Proposed Case-Mix Adjustment

Comment: Several comments indicated that the proposed age groups were too broad. Some of the comments recommended that we create more age categories for purposes of the case-mix adjustments.

Response: In the proposed rule we established three age categories for example: less than 65, 65–79, and greater than 79. In reassessing the study sample and the proposed case mix adjusters, we also explored the age categories. We concur with the comments to expand the number of age categories. For the final rule, there will be five age groupings. These are: 18–44, 45–59, 60–69, 70–79, and 80+. Patients under 18 are discussed in the following section on pediatrics. We believe that the revisions to the age groupings more accurately describe the distribution of the patient population and reflect more refined predictors of age for payment purposes.

Comment: One commenter asked what would happens under our proposed adjustment if during the course of a month, an ESRD patient's age changed and they cross the line into another case-mix adjustment factor. For example, on August 15 a 64-year-old ESRD patient turns 65. They questioned how is this situation is handled and is the age used as of the last day of the month.

Response: We believe it is appropriate to handle this situation as it is handled for enrollment. Thus, for a month when the patient has a birthday that puts him or her into another age category, the first of the month would be the effective date of the patient's new age category.

5. Case-Mix Adjustment for Pediatric Patients

Comment: Several commenters expressed concern over the lack of a case-mix adjustment for pediatric ESRD patients. The commenters stated that although section 623(b) of the MMA provided for an exception process for pediatric ESRD facilities, qualification for a pediatric exception is limited to those facilities where pediatric patients (those under age 18), comprise at least 50 percent of the caseload. The commenters pointed out that ESRD pediatric patients are unusually resource intensive and costly and are widely scattered among facilities, most of which would not qualify as pediatric facilities under the definition set forth in the statute. The commenters recommended that we develop a case-mix adjuster for pediatric ESRD patients using other data sources.

Response: Using the same regression methodology described in the proposed rule, we attempted to develop a case-mix adjuster for outpatient ESRD patients under age 18. However, based on the approximately 600 Medicare patients for whom bills were available each year from 2000 through 2002, the results were highly variable, statistically

unstable, and therefore inappropriate for development of a case-mix adjuster in accordance with the proposed rule's methodology. However, because of the costliness of pediatric ESRD patients, we believe that an alternative case-mix adjustment is warranted, particularly for those facilities, which do not meet the definition of a pediatric facility under section 623(b) of the MMA.

As the commenter correctly pointed out, some facilities would not qualify for consideration for the pediatric exception provided in the law because their pediatric caseload does not constitute 50 percent of their patients. These facilities may still incur substantial costs for the treatment of pediatric ESRD patients. Pending the development of more refined case-mix adjustments that are more sensitive to individual variation in treatment costs under a fully bundled ESRD PPS, we are providing for a single adjustment to a facility's otherwise applicable composite payment rate, developed based on the methodology described below, for outpatient ESRD pediatric treatments. We want to emphasize that the pediatric adjustment factor resulting from this methodology is intended to be a temporary measure. It will only apply until we can develop an adjustor under the bundled ESRD PPS that is more similar with the case-mix adjustments that would apply to non-pediatric ESRD patients.

During the period from November 1, 1993 to the present time, we identified 19 hospital-based and one freestanding ESRD facility, each of which sought and received an atypical services exception based on the higher costs incurred for the treatment of outpatient pediatric patients. For each of these facilities we obtained the number of treatments at the time the exception was submitted and determined the unadjusted composite payment rate that would have applied beginning January 1, 2005 without regard to any exception amount, that is, each facility's unadjusted composite payment rate was inflated to January 1, 2005 to reflect the statutory increases of 1.2 percent effective January 1, 2000, 2.4 percent effective January 1, 2001, and 1.6 percent effective January 1, 2005.

We then subtracted the inflated January 1, 2005 unadjusted composite rate from each facility's composite payment rate, including the exception amount granted, to obtain the estimated amount of the exception projected to 2005. This amount was multiplied by the number of treatments previously provided, summed for all 20 facilities, and then divided by the number of treatments for all 20 providers to yield an average atypical services exception amount per treatment. The average exception amount for ESRD facilities that received exceptions due to their pediatric caseload, adjusted to 2005, was $86.79 per treatment. The average unadjusted composite payment rate for these same 20 facilities projected to 2005, similarly weighted by the number of treatments, was $139.32. Thus, the average composite payment rate adjusted to January 1, 2005, including the average exception amount of $86.79, was $139.32 + $86.79 or $226.11. Because the average exception amount was calculated from facilities located in areas with differing wage levels, we converted the average pediatric exception amount to a ratio, $226.11/$139.32 or 1.62.

This is the case-mix adjustment factor that will be applied to each facility's composite payment rate per treatment for outpatient maintenance dialysis services furnished to pediatric patients. This includes both in-facility and home dialysis. Applying the adjuster multiplicatively in this manner recognizes the wage index variation in labor costs among urban and rural areas built into the composite rates. Notwithstanding this case-mix adjustment per treatment for ESRD pediatric patients, facilities who otherwise qualify as a pediatric facility under section 623(b) of the MMA will be permitted to seek an exception to this rate if they believe their circumstances warrant a higher payment rate under the atypical services exception provisions set forth in the regulations. We intend the pediatric adjustment factor of 1.62 to be a temporary measure. We anticipate its elimination once the case-mix methodology that will apply in the context of the bundled ESRD PPS is developed. We want the same methodology to apply to both pediatric and non-pediatric ESRD patients.

6. Facility Level Control Variables Used in the Proposed Regression Model

In developing the regression model used to derive the case-mix adjustments, we included variables reflective of facility characteristics. Because facility characteristics do account for differences in facility composite rate costs, we included them in the regression model through the use of facility control variables, so that the patient characteristic case-mix adjusters are not distorted. The facility control variables included the wage index, facility size (based on the annual number of treatments), facility status as hospital-based or freestanding, percent of patients with urea reduction ratios greater than or equal to 65 percent, chain ownership, year of cost report, and percent of pediatric patients treatments. These variables were not used to calculate the basic case-mix adjustment factors.

Comment: One comment questioned the inclusion of the proportion of patients with urea reduction ratios (URRs) greater than 65 as a facility control variable in the least squares regression model used to develop the case-mix adjustment factors. The comment maintained that because a patient's URR may be correlated with other co-morbid conditions, the coefficients for the variables tested in the model might be distorted. The comment recommended an evaluation of the degree of association between URR and the main co-morbid conditions to determine the extent of any multicolinearity. The comment further stated that if URR is appropriate as a facility control variable, then other surrogates of dialysis efficiency, such as standardized mortality ratio and proportion of patients with hemoglobin readings above specified target levels, should also be considered as control variables.

Response: We believe that case-mix adjustments to the composite payment rate must be determined by patient and not by facility characteristics. To the extent that facility differences in costs are statistically explained by facility and not patient characteristics, we account for them in the regression model through the use of control variables, so that the potential case-mix adjusters are not distorted. Facility control variables were not used to develop the adjustment factors to the composite payment rates.

For example, chain affiliation, facility size, and status as a hospital-based or freestanding facility were associated with statistically significant differences in facility costs. However, it would be inappropriate to object to the payment rates based on a facility belonging to a particular chain, or based on the number of annual treatments.

To test for multicolinearity, that is, to ensure that each co-morbidity tested for inclusion in the regression model was not correlated with other variables, we ran a correlation matrix. The correlation matrix included URR. URR was found not to correlate with any of the co-morbidities tested; in statistical parlance, it was orthogonal. Accordingly, low URR was not a surrogate of co-morbidity. Therefore, we believe it was appropriate to treat URR as a quality of care outcome measure at each facility. The effect of using URR as a facility control variable was to ensure that the case-mix adjustment factors were not distorted for facilities with similar URR outcomes. For example, if

larger patients receive lower doses of dialysis, not controlling for URR could impart a downward bias on the coefficient for patient size. The comment also suggested the use of other variables as facility control variables such as standardized mortality ratio (SMR) and hemoglobin count. Because SMR standardizes or controls for the effect of case mix on the ratio, we would have to ensure consistency in the reporting of specified co-morbidities on the bills in order to ensure the validity of each facility's SMR. That consistency currently does not exist. Facilities are only required to report hematocrit/hemoglobin on the claims available for those patients receiving erythropoeitin (EPO). However, because the proportion of patients receiving EPO is high, the use of hematocrit/hemoglobin as another outcome facility control variable is feasible, but mainly in the context of the bundled payment system. Since the drugs and lab tests associated with anemia management are paid outside the composite payment rate, hematocrit/hemoglobin level would not be appropriate as a control variable applicable to composite rate costs.

7. Propriety of Case-Mix Adjustment

Comment: Several commenters expressed reservations about our proceeding with the implementation of a case-mix adjustment to the composite payment rates using the methodology set forth in the proposed rule. One commenter cited the May 19, 2004 report prepared by the KECC of the University of Michigan, which pointed out that the proposed case-mix variables collectively explained less than 1 percent of the facility variation in composite rate costs, although the addition of facility control variables increased this proportion to about 33 percent. One commenter stated that the low explanatory power of the proposed case-mix variables indicated that they do not accurately predict cost variation and are flawed. The commenter suggested that we defer applying a case-mix model until the results of the demonstration project mandated under section 623(e) of the MMA are available.

Response: We would have preferred to develop a case-mix adjustment in the context of a bundled outpatient ESRD PPS. In a fully bundled PPS, which section 623(f) of the MMA anticipates, routine and separately billable dialysis related services, drugs, and clinical laboratory tests would be included in the payment bundle. KECC's previous research revealed that, for separately billable services, case-mix explained about 23 percent of the variation in cost across dialysis facilities. (*See* Hirth, *et al.*, Is Case-Mix Adjustment Necessary for an Expanded Dialysis Bundle?, Health Care Financing Review, 2003, 24, pages 77–88).

However, the enactment of Pub. L. No. 108–173 foreclosed the option of deferring implementation of a casemix adjusted composite rate based on a limited number of patient characteristics effective January 1, 2005. We do not believe that the statutory directive set forth in section 623(d) of the MMA permits us to defer the development of a basic case-mix measure, one based on a ''limited number of patient characteristics.''

We do not agree with the statement that, because the proposed case-mix adjusters collectively account for about 1 percent of the facility variation in composite rate costs, the variables used are fundamentally flawed. In fact, when data is combined over three years, each of the proposed case-mix variables is highly significant statistically, despite the low proportion of facility variation in costs explained. A more important indicator of the importance of the case mix factors identified is the size of the adjustments. If the identified case mix variables did not have a meaningful relationship with costs, the magnitude of the adjustment factors would be insignificant or trivial. They are not. As explained in this final rule, based on our analysis of the comments we received, we have revised the case-mix variables used to adjust the composite payment rates. Our research to develop a statistically robust clinically coherent case-mix measure in the context of the fully bundled ESRD PPS will continue.

8. Alternative Case-Mix Variables

Comment: Several commenters suggested alternative case-mix variables which they believe account for patient differences in resource consumption and would better distinguish facility differences in composite rate costs. The patient characteristics proposed by commenters included quarterly serum albumin values, cancer, limb amputation, gastrointestinal disorders, body mass index, weight, revised age groupings, hypertension, duration of dialysis treatment, and others. The commenters indicated that, based on their clinical judgment, the suggested factors were more likely to be predictors of variability in the cost of care than the proposed AIDS and PVD co-morbidities. A few commenters recommended a delay in the implementation of the case-mix adjusted composite payment rates pending evaluation of the suggested variables. A number of comments indicated that BMI was a significant predictor of cost and recommended that BMI be included in the case-mix adjustment. Another commenter recommended BSA be examined as a potential case-mix predictor.

Response: We appreciate all of the comments we received proposing alternative case-mix variables. We welcome suggestions for case-mix refinement based on sound clinical judgment, especially when analyses including separately billable ESRD services are performed as our research for development of the bundled ESRD payment system progresses. However, we point out, that unless the existence of a suggested co-morbidity or patient characteristic could be determined from either the Form CMS 2728 or claims data which could be linked to a specific ESRD dialysis patient, we were unable to evaluate its potential to predict facility differences in composite rate costs. Furthermore, unless a patient characteristic can be reported on the UB 92 claim form (or the equivalent electronic version), it cannot be used to adjust a facility's composite payment rate. These limitations eliminate for consideration many of the commenters' suggested alternative patient characteristic variables.

Nonetheless, our regression model evaluated 35 patient characteristics including weight, BMI, BSA, seven types of cancer, diabetes, chronic obstructive pulmonary disease, four types of heart disease, and race. Co-morbidities selected for inclusion in the model with significant negative coefficients were removed from subsequent iterations of the stepwise regression model. The inclusion of such co-morbidities would have resulted in reductions in the otherwise applicable composite rate payments. Because we can now require the reporting of height and weight on the claim form beginning January 1, 2005, we have adopted the commenters' suggestions to use either BMI or BSA as a predictor variable. We selected BSA and low BMI because they improve the model's ability to predict the costs of composite rate service compared to using BMI or weight alone. In addition, we have increased the number of age groups from three to five and eliminated gender as a payment variable entirely.

As explained later in the ''Implementation Date'' section, we do not believe it would be appropriate to further delay the implementation of the basic case-mix adjustment. We proposed delaying implementation of the case-mix payments until April 1, 2005 in order to ensure all systems, programming, and other operational requirements are in place. Between publication of this final rule and the

implementation date, we will conduct training programs to ensure that facilities understand both the payment methodology and reporting requirements necessary to ensure appropriate payment to ESRD facilities.

9. Continuing Research To Develop a More Fully Bundled Case-Mix System

Comment: Several comments requested additional detail regarding the continuing research for the development of a more fully bundled system.

Response: The research activities for the fully bundled system have focused on updating the database. Research efforts since the passage of MMA have focused on supporting the Congressional mandate for the development of a limited number of case-mix variables. Following the publication of this rule, we anticipate that the emphasis will return to the development of a bundled prospective payment system that includes bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. This research will be reflected in an October 1, 2005 Report to the Congress.

In addition, the MMA requires us to establish the fully case-mix adjusted demonstration which will bundle into the payments both separately billable drugs and biologicals and clinical labs. Both the Report to the Congress and the demonstration will be supported by continuing research.

10. Body Measurements as Case-Mix Adjusters

In the proposed rule, we had discussed the importance of the BMI as a measure of resource consumption related to the composite payment rate. At that time, our analysis indicated that patients with very low or high BMI were more costly to treat. At the time of the publication of the proposed rule, we had no mechanism to obtain indicators for height and weight on the claims form. We had indicated that we would be exploring adding height and weight to the bills.

Comment: A number of commenters endorsed the use of low BMI as an appropriate surrogate for the severity of morbid conditions associated with malnourishment in the dialysis population, and some suggested that a BMI below 20.0 kg/m^2 is generally considered in the underweight range. In addition, we also received comments regarding the inclusion of a measure of BSA.

Response: We concur with the comments to include BMI and BSA as case-mix adjusters reflecting patient characteristics that explain variation in the reported costs for composite rate services. We have obtained approval to collect both height and weight on the bill through the use of two new value codes. ESRD facilities will be required to report height and weight using these value codes, so that payment can be based on the case-mix adjusted composite rate payment system on April 1, 2005.

For the implementation of the basic case-mix payments, we are providing an adjustment for low BMI, that is, any patient with a BMI less than 18.5 kg/m^2. We included this variable because our regression analysis indicated that those patients who are underweight and malnourished consume more resources than other patients. Although we received one comment suggesting defining low BMI as 20 kg/m^2, we chose the measure of low BMI that is consistent with the CDC and NIH definition for malnourishment. Furthermore, our exploration of alternative BMI thresholds did not improve the model's ability to predict the costs of composite rate services.

In addition, we are providing case-mix adjustments based on BSA. Our research into this body measurement indicated that BSA (meters^2) is a good predictor of composite rate resource consumption. We examined all of the formulas for BSA. While we found very little differences between the formulas in predictive power, we are adopting the Dubois and Dubois formula for BSA since our literature search revealed that this particular formula was the most widely known and accepted. This formula is: $BSA=W^{0.425} * H^{0.725} * 0.007184$ (DuBois D. and DuBois, EF. ''A Formula to Estimate the Approximate Surface Area if Height and Weight be Known'': Arch. Int. Med. 1916 17:863–71.), where w and h represent weight in kilograms and height in centimeters, respectively.

In addition, we explored a number of options for setting the reference values for the BSA. We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on this analysis, we are setting the reference point at a BSA of 1.84 (the average BSA among dialysis patients in 2002). By setting the reference point at the average BSA, the adjusters will reflect the relationship of a specific patient's BSA to the average BSA of all patients. Therefore, some adjusters will be greater than 1.0 and some will be less than 1.0. In this way, we are able to minimize the magnitude of the budget neutrality offset to the composite payment rate.

The following presents an example of the method for calculating patient level multipliers that were derived from the coefficients resulting from the regression model that includes control variables, expanded age groups, BSA, and an indicator for low BMI (<18.5 kg/m^2). The model excluded small facilities, and outliers.

Case-mix adjuster = Age factor * low BMI factor * BSA factor

Although we could have selected any increment, we believed an increment of 0,1 provided and appropriate degree of precision of the calculation of the exponent used to compute the BSA case-mix adjustment. The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.84 divided by 0.1. The BSA adjustment factor of 1.037 is then exponentiated based on the calculated BSA factor as 1.037 ((BSA - 1.84)/0.1)

For Example: The case-mix adjuster for a 47-year old person who is underweight (BMI<18.5 kg/m^2) and has a body surface area of 2.0 m^2 is calculated by using the 1.84 BSA reference point:

Age Factor = 1.055
Low BMI Factor = 1.112
BSA Factor = $1.037\ ((2.0-1.84)/0.1) = 1.037^{(1.6)} = 1.060$
Case-Mix Adjuster = 1.055 * 1.112 * 1.06 = 1.244

The resulting case-mix adjustment factor of 1.244 for this patient would be applied to the facility's composite payment rate that is adjusted for area wage index, drug add-on, and budget neutrality.

11. Budget Neutrality for Case-Mix Adjustment

Section 1881(b)(12)(E)(i) of the Act, as added by section 623(d)(1) of the MMA, requires that the basic case-mix adjusted composite rate system be designed to result in the same aggregate amount of expenditure for such services, as estimated by the Secretary, as would have been make for 2005 if that paragraph did not apply. Therefore, the patient characteristics case-mix adjustment required by section 623(d)(1) of the MMA must result in the same aggregate expenditures for 2005 as if these adjustments were not made.

In order to account for the payment effect related to the case-mix adjustment, we proposed to standardize the composite rate by dividing by the average case-mix modifier of 1.1919. The proposed budget neutrality adjustment to the composite rate was 0.8390. However, we were not able to simulate case-mix effects at the bill level

because co-morbidities are generally not reported on the ESRD bill. We still intend to refine our case-mix adjustments once we have more complete patient data on the ESRD bill. In this final rule, we have refined our adjustment for budget neutrality related to the case-mix factor. We simulated payment for each ESRD provider by applying a facility-specific case-mix multiplier to the composite rate applicable for that facility. Since the pediatric case-mix adjustment was developed outside the regression model, we simulated payments separately for those treatments. The results of these tow computations were then combined to arrive at the total case-mix adjusted payments. We also simulated payment for each provider as if they did not receive any case-mix adjustments. We then compared the total simulated payments with case-mix adjustment to total simulated payments without case-mix adjustment. The resulting budget neutrality adjustment to the composite rate is 0.9116.

B. Revised Patient Characteristic Adjustments

The following section discusses in detail the final case-mix adjustments to the ESRD composite rate payment.

In summary, based on the comments that we received on the proposed case-mix and additional analyses prepared by our contractor, KECC, in this final rule, we are modifying the proposed case-mix adjustments. We have broadened the number of age groups to include five age categories and added low BMI and BSA as measures. We have also included a specific case-mix adjustment for pediatric patients under age 18. We excluded the proposed categories gender and co-morbid conditions. We will be using a limited number of patient characteristics for the basic case mix system; however, we believe that these adjustments adequately explain variation in the reported costs per treatment for the composite rate services consistent with the legislative requirement. The adjustment factors for the basic case mix are listed in Table 13 below.

TABLE 13:

Variable		Multiplier
Age	Pediatrics <18 **	1.62
	18-44	1.223
	45-59	1.055
	60-69	1.000
	70-79	1.094
	80+	1.174
Body Surface Area (per 0.1 Δ BSA of 1.84)		1.037
Low BMI (<18.5 kg/m^2)		1.112

** BSA and BMI adjustment do not apply to pediatric patients.

The following table illustrates the average case-mix adjustment by type of provider based on the 2002 data that was used to develop the adjustment factors.

Table 14:

Facility Type	Average Case-Mix Adjustment
All	1.0967
Independent	1.0963
Hospital-Based	1.0990
Urban	1.0957
Rural	1.1009
Small (<5k treatments/yr.)	1.1027
Medium (<5-10k treatments/yr.)	1.0995
Large (>10k treatments/yr.)	1.0947
Non-Profit	1.1004
For-Profit	1.0957

As illustrated in table 14, regardless of the type of provider, the projected average case-mix adjustments for patient characteristics do not vary significantly.

C. Rural Facilities

Comments: Some commenters focused on the potential impact the revised composite rate payment system could have on rural facilities. They were initially concerned that excluding small facilities from the overall sample actually reflected the elimination of rural facilities from the sample. As a means of resolving this issue, they suggested that a rural facility exception be restored.

Response: The MMA provision for composite rate exceptions limited the availability of exceptions only to pediatric facilities. To the extent that a qualifying pediatric facility is located in a rural area, it would be able to apply for an exception to its composite payment rate.

D. Dual Eligible Dialysis Population

Comment: One commenter expressed concerns regarding potential impact on the dual eligible population, specifically with respect to coverage of deductibles and coinsurance amounts. Concern was expressed regarding the impact of this proposal on the Medicaid population on a state-by-state basis.

Response: We recognize that this is an important issue for ESRD facilities and can be particularly problematic for chain organizations that own facilities in multiple States. While we cannot direct States for payment for dual eligible beneficiaries, we will take appropriate action to ensure that States are aware of the changes we are implementing so they can take steps to adjust their payments for dual eligible dialysis patients.

E. Budget Neutrality

Section 623(d)(1) of the MMA added section 1881(b)(12)(E)(i) of the Act, which requires that the basic case-mix adjusted composite rate system be designed to result in the same aggregate amount of expenditure for services, as estimated by the Secretary, as would have been made for 2005 if that paragraph did not apply. Therefore, the drug add-on adjustment and the patient characteristics case-mix adjustment required by section 623(d)(1) of the MMA must result in the same aggregate expenditures for 2005 as if these adjustments were not made.

For the proposed drug payment add-on adjustment, we indicated in the proposed rule that the methodology we used to estimate the difference between the current and proposed drug payments was designed so that aggregate payments would be budget neutral.

In addition, the proposed rule provided for a budget neutrality adjustment to the composite payment rate of 0.8390 to account for the effects of the proposed case-mix adjustments on aggregate expenditures.

Comment: We received a number of comments concerning our application of the budget neutrality provision of section 623 of MMA. Specifically, many comments suggested that we did not comply with Congressional intent that facilities would be held harmless by this provision, that is, that facilities would not receive lower payments then they otherwise would have.

Response: Section 623 of MMA requires that aggregate payments in 2005 not exceed payments that would otherwise be paid. The budget neutrality provision is to ensure that total aggregate payments from the Medicare trust fund will not increase or decrease as a result of changes in the payment methodology. As with other Medicare payment systems, changes in the payment mechanism will result in the redistribution of Medicare dollars across facilities. There is no provision (nor any implication) in section 623 of the MMA that guarantees that individual facilities would receive the same amount of payment under a case-mix adjusted system as they did previously.

The final budget neutrality adjustment to the ESRD composite payment rate applicable to the case mix adjustments (including the pediatric adjustment) is 0.9116. Also in the proposed rule, the calculation of the drug add-on adjustment was designed to ensure budget neutrality with respect to aggregate drug payments.

F. Geographic Index

Comment: Several comments expressed disappointment that we did not propose revisions to the current outdated wage indexes reflected in the composite payment rates, despite the discretionary authority set forth in section 623(d)(1) of the MMA to replace them. These comments stated that this decision likely would have the greatest impact on facilities located in high cost and high wage areas, where competitive labor market pressures are more

pronounced. Comments generally were in favor of using the most up-to-date information available for developing a revised composite rate wage index.

Response: The wage index currently used in the composite rates is a blend of two wage index values, one based on hospital wage data from fiscal year 1986 and the other developed from 1980 data from the Bureau of Labor Statistics. The wage index is calculated for each urban and rural area based on 1980 U.S. Census definitions of metropolitan statistical areas (MSAs) and areas outside of MSAs. Restrictions apply to the wage index values used to develop the composite payment rates. Payments to facilities in areas where labor costs fall below 90 percent of the national average, or exceed 130 percent of that average, are not adjusted below the 90 percent or above the 130 percent level. This effectively means that facilities located in areas with wage index values less than 0.90 are paid more than they would receive if we fully adjusted for area wage differences. Conversely, facilities in locales with wage index values greater than 1.30 are paid less than they would receive if we fully adjusted payment for these higher wage levels.

We agree that the current ESRD composite rate wage indexes, and the definitions of the geographic areas on which they are based, need to be updated. On June 6, 2003, OMB issued Bulletin 03–04, which announced new geographic areas based on the 2000 Census. The extent to which we use the new OMB geographic definitions, incorporate them into the various prospective payment systems (PPSs) we administer, and whether we rely on hospital wage and employment data to develop new composite rate wage index values will have the potential to significantly redistribute payments among ESRD facilities.

In the August 11, 2004 **Federal Register** (69 FR 48916), we announced how we were revising the hospital wage index used in connection with inpatient PPS. Although one comment stated that we should adopt the same wage index used in connection with the inpatient PPS, several of the hospital wage index revisions stem from specific provisions of law (for example, geographic reclassification of hospitals) and would not necessarily be appropriate to apply to a revised ESRD wage index for the composite payment rates. Because of the discretion afforded the Secretary in developing a new wage index for ESRD payment purposes, we are carefully assessing the propriety and payment implications of policy options before recommending revisions to the current measure. We will not take action to replace the current composite rate wage index at this time. We point out that, in accordance with section 623(d)(1) of the MMA, any revisions to the wage index ultimately adopted must be phased in over a multiyear period.

G. Payment Exceptions and the Revised Composite Payment Rate

1. Application of Statutory Increases to Exception Amounts

Comment: Several comments were critical of our policy of not applying increases to composite rates, mandated by the Congress, to amounts paid under exceptions. The comments maintained that this policy is inequitable, precludes the proper application of inflation updates to costs that we had recognized as appropriate in granting the exception, and over time erodes the value of the exception because of the cumulative impact of an effective ''historical freeze.''

Response: The commenters are correct that we have only applied the Congressionally mandated statutory increases to the basic wage index adjusted composite payment rates, not to exception payments. For example, a provider which was authorized a $12.00 atypical services exception amount per treatment in addition to its otherwise applicable composite payment rate of $125.00 effective August 12, 2000 would not be entitled to the 2.4 percent increase applicable to composite rate payments on January 1, 2001, because its exception rate of $137.00 exceeded its basic rate of $125.00 increased by 2.4 percent or $128.00. While the commenter believes that our policy of not applying the Congressional mandated increases to exception amounts is unfair, we believe that the policy is consistent with the law. Section 422(a)(2)(C) of SCHIP, enacted December 21, 2000, states as follows in pertinent part:

> Any exception rate under such section in effect on December 31, 2000 * * * shall continue in effect so long as such rate is greater than the composite rate as updated * * *.

Thus, the statute seems to distinguish between an exception rate and the composite rate, as ''updated'' by the Congress. The clear implication of the text is that the exception rate is not so updated. Accordingly, we believe that our policy of not applying mandated composite rate increases to exception amounts is consistent with the statute. Moreover, we point out that section 422(a)(2) of SCHIP prohibited the granting of new exceptions and that we are providing facilities the option of either retaining their exception rates, or at any time, electing payment under the case-mix adjusted composite payment rates. We do not believe providers, given this option, will be disadvantaged.

2. Home Dialysis Training Exceptions

Comment: We received comments asking for clarification concerning home dialysis training exceptions since the proposed rule only addressed exceptions in a very general way. They stated that the rule proposes that each facility with an exception rate would compare their exception rate to the new basic case-mix adjusted prospective payment and then decide if it wishes to withdraw the exception rate and be subject to the basic case-mix adjusted composite rate. The commenters stated that this language does not consider a facility that would choose to accept the basic case-mix adjusted prospective payment for its chronic treatments, but continue its exception rates for the training of home patients. The home training exception is the most widely used exception and provides a higher rate for the higher cost of training a patient in fewer than the maximum number of allowed treatments.

Response: We agree and are providing that a home training exception rate may be continued. Facilities with home training exceptions will be able to retain their current exception training rates as well as take advantage of the case-mix adjusted rate for non-training dialysis.

3. New Exception Window

Comment: One commenter requests that a new ''exceptions window'' for pediatric facilities be opened in early 2005. It will not be until after this rule is final that its members will be able to determine the exact impact of this new methodology on their operations.

Response: Section 623(b) of MMA reinstated exceptions for qualifying pediatric facilities defined as facilities with at least 50 percent of their patients under 18 years of age. The current exception window for pediatric facilities closed on September 27, 2004. At this time, future exception windows will be open only for pediatric facilities. The exceptions process is opened each time there is a legislative change in the composite payment rate or when we open the exception window. The fiscal intermediary will notify the ESRD pediatric facilities when a new exception window opens. However, it is our intent to open pediatric exception windows on an annual basis.

4. Home Dialysis Training Rates

Comment: One commenter asked if the training rate add-on to the composite rate would still be applied.

Response: Yes, the following rates will apply for self-dialysis or home dialysis training sessions:

- For intermittent peritoneal dialysis (IPD), continuous cycling peritoneal dialysis (CCPD) and hemodialysis training, the facility's case-mix adjusted payment excluding any approved exception rates will be increased by $20 per training session, furnished up to three times per week.
- For continuous ambulatory peritoneal dialysis (CAPD), the facility's case-mix adjusted payment excluding any approved exception rates will be increased by $12 per training session, furnished up to three times per week.

Based on the example for John Smith in section L (Example of Payment Calculation Under the Case-Mix Adjusted Composite Rate System), the hemodialysis (IPD & CCPD) training rate would be his case-mix adjusted rate of $170.80, increased by the training add-on of $20 for a total training rate of $190.80. For CAPD training, the training rate would be $182.80 ($170.80+$12)

H. Implementation Date

Comment: We received a number of comments supporting our proposed delay in implementing the case-mix portion of the revised composite payment methodology. Many comments maintained that the proposed April 1, 2005 effective date was overly ambitious, and some suggested that a July 1, 2005 implementation date would be more realistic given the need for facility and fiscal intermediary training and education.

Response: The MMA requires that the basic case-mix adjusted composite payment rates be effective for services beginning January 1, 2005. Despite the statute's specificity, we pointed out in the proposed rule that all of the numerous systems, programming, and operational changes necessary to implement the case-mix adjusted payments cannot be completed in time for a January 1, 2005 implementation date.

As presented in the proposed rule, we considered two options that we believed effectively complied with the statute's January 1, 2005 implementation date. While we stated in the proposed rule that either of these options substantively complies with the January 1, 2005 implementation date requirement of the statute, we rejected both alternatives.

The likelihood of payment error, potential disruption of facility payments, and the cost of reprocessing bills militated against either option. We proposed instead an April 1, 2005 implementation date for the basic case-mix adjustments to the composite payment rates, including the budget neutrality reduction. This option avoids the need for reprocessing of bills and applies the budget neutrality adjustment applicable to the case-mix adjustments effective April 1, 2005. Although we agree with the comment that a July 1, 2005 effective date would be ideal in light of the systems and operational changes required to implement the case-mix provisions, we believe that an April 1, 2005 effective date for the case-mix adjustments is feasible, and have decided not to revise that date. We have concluded based on our evaluation of ESRD claims processing systems that the April 1, 2005 implementation date is achievable. As we stated in the proposed rule, the 1.6 percent increase to the composite payment rates and drug add-on will be effective January 1, 2005.

I. Summary of Final Rule Implementing Changes to the ESRD Composite Payment Rate (Section 623 of MMA)

As set forth in this final rule, we will increase the ESRD composite payment rates by 1.6 percent effective January 1, 2005 in accordance with section 623(a) of the MMA. Also, the composite payment rates will be increased January 1, 2005 by 8.7 percent to reflect revisions to the drug pricing methodology for separately billable drugs, as discussed previously in this rule (Composite Rate Adjustments to Account for Changes in Pricing of Separately Billable Drugs and Biologicals). This section explains the development and computation of the revised drug add-on, which differs from the 11.3 percent amount described in the proposed rule, and our response to comments which advocated separate add-on amounts for hospital-based and independent facilities.

Despite the discretionary authority set forth in section 623(d)(1) of the MMA to replace the current outdated wage index used in the composite payment rates, we are taking no action to revise the wage index at the present time. A revised wage index will potentially significantly redistribute ESRD payments. We believe that further study is warranted before we revised the current index. Those assessments are presently underway.

We have also adopted a revised basic case-mix methodology for adjusting the composite payment rates based on a limited number of patient characteristics, as prescribed in section 623(d) of the MMA. The development and application of the revised case-mix adjusters were previously explained in the ''Revised Patient Characteristic Adjustments'' section of this final rule. The variables for which adjustments will be applied to each facility's composite payment rate include age, BSA, and low BMI. In response to comments, we eliminated gender in this final rule as a patient classification variable for purposes of case-mix adjustment, substituting BSA and a low BMI variable instead. We have also increased the number of age categories from three to five, and eliminated co-morbidities pending further study. Because height and weight are necessary to compute each patient's BSA and BMI, those measurements, in centimeters and kilograms, respectively, will be required on the UB 92 for outpatient ESRD services furnished on and after January 1, 2005. This final rule also provides for a case-mix adjustment of 1.62 to a facility's composite payment rate for pediatric ESRD patients (that is, under age 18). The methodology used to develop the pediatric case-mix adjustment factor of 1.62 is described in the ''Case-Mix Adjustment for Pediatrics Patients'' section of this rule. Although the MMA requires that the basic case-mix adjusted composite payment rates be effective for services beginning January 1, 2005, the systems and operational changes necessary to implement them cannot be completed in time for a prospective January 1, 2005 effective date. The case-mix adjustments and the applicable budget neutrality adjustment of 0.9116 will be effective April 1, 2005.

Example of Payment Calculation Under the Case-Mix

Example 1

Adjusted Composite Rate System

The following example presents 2 patients dialyzing at Neighbor Dialysis, an independent ESRD facility located in Baltimore, MD.

Calculation of Basic Composite Rate for Neighbor Dialysis

Wage adjusted composite rate for independent facilities in Baltimore, MD: $134.93

Wage adjusted composite rate increased by drug add-on adjustment $134.93 × 1.087: $146.67

Adjusted Facility Composite Rate after budget neutrality adjustment ($146.67 × 0.9116): $133.70

Patient #1

John Smith attains age 18 on April 10, 2005 and undergoes hemodialysis. John

weighs 75.5 kg. and is 181.5 cm. in height. Because John Smith attains age 18 April 10, he is considered age 18 for the entire month of April, and would not be classified as a pediatric patient.

Calculation of Case Mix Adjusted Payment

The BSA and BMI for John Smith will be calculated by the PRICER program used to compute the composite payment for each patient based on the height and weight reported on the UB 92. However, the computations of the BSA and BMI for John Smith are shown below:

BSA = $0.007184 \times (\text{height})^{0.725} \times (\text{weight})^{0.425}$

BSA = $0.007184 \times 181.5^{0.725} \times 75.5^{0.425}$

BSA = $0.007184 \times 43.4196 \times 6.2824 = 1.960$

BMI = $\text{weight}/\text{height(m)}^2$

John Smith is 181.5 cm. in height, which converts to 1.815 meters.

BMI = $75.5/1.815^2 = 22.919$

The case mix adjustment factor for John Smith, an 18 year old whose BMI exceeds 18.5 kg/m^2 and has a BSA of 1.960 is calculated as follows:

Age adjustment factor (age 18–44) 1.223

BMI adjustment factor (BMI ≥ 18.5 kg/m^2) 1.000

BSA adjustment factor ($1.037^{1.960-1.84/0.1}$) 1.0446

Case mix adjustment factor ($1.223 \times 1.000 \times 1.0446$) 1.2775

Basic case mix adjusted composite payment ($133.70 \times 1.2775) $170.80

Patient 2

Jane Doe is a 82 year old malnourished patient who undergoes hemodialysis. Jane is 158.0 cm. in height.

Calculation of Case Mix Adjusted Payment

The BSA and BMI for Jane Doe, which will be automatically computed by the PRICER program, are calculated as follows:

BSA = $0.007184 \times (\text{height})^{0.725} \times (\text{weight})^{0.425}$

BSA = $0.007184 \times 158.0^{0.725} \times 31.25^{0.425}$

BSA = $0.007184 \times 39.2669 \times 4.3183 = 1.2182$

BMI = $\text{weight}/\text{height(m)}^2$

Jane Doe is 158 cm. in height, which converts to 1.580 meters.

BMI = $31.25/1.580^2 = 12.5180$

The case mix adjustment factor for Jane Doe, an 82 year old whose BMI is less than 18.5 kg/m^2 and has a BSA of 1.2182, is calculated as follows:

Age adjustment factor (age 80+) 1.174

BMI adjustment factor (BMI ≤ 18.5 kg./m^2) 1.112

BSA adjustment factor ($1.037^{1.2182-1.84/0.1}$) 0.7978

Case-mix adjustment factor ($1.174 \times 1.112 \times 0.7978$) 1.0415

Basic case mix adjusted composite payment ($133.70 \times 1.0415) $139.24

Example 2

Linda Jones is age 16 and undergoes peritoneal dialysis at Community Hospital, a hospital-based facility in New York City. Linda weighs 35 kg and is 160.0 cm in height. The basic composite rate for Linda Jones is calculated as follows:

Wage adjusted composite rate for hospital-based facilities in New York, New York: $146.35

Wage adjusted composite rate increased by drug adjustment factor ($146.35 × 1.087): $159.08

Adjusted Facility Composite Rate after budget neutrality adjustment ($159.08 × 0.9116) $145.02

Because Linda is a pediatric ESRD patient, the automatic pediatric adjustment factor of 1.62 applies. Neither the age, BMI, nor BSA adjustments are applicable because Linda is less than age 18.

Pediatric adjusted composite rate ($145.02 × 1.62) $234.93

If Community Hospital were entitled to a composite rate exception, then the provider could elect to retain its exception rate in lieu of receiving the otherwise applicable pediatric payment rate of $234.93.

Impact Analysis

Comment: One commenter observed that the budgetary impact on the Medicare program of proposed section 623 changes (impact table) generally indicates an ''overall'' neutral or modest reimbursement increase for all types of dialysis facilities (independent and rural, for profit and non-profit, urban and rural). This commenter requested data that indicate the number of dialysis facilities that are operating at a loss in the U.S., by corresponding facility characteristics shown in the impact table.

Response: The purpose of the impact table is to simulate what ESRD facilities will receive in payments under the MMA section 623 changes compared to what ESRD facilities would receive without any changes to the current composite payment rates. We do not have data to determine whether or not a facility may operate at a loss under MMA section 623.

J. Section 731—Coverage of Routine Costs for Category A Clinical Trials

Before the enactment of the MMA, Medicare did not cover services related to a noncovered Category A device. The MMA authorizes Medicare to cover the routine costs associated with certain Category A clinical trials for services furnished on or after January 1, 2005. For a trial to qualify for payment, it must meet certain criteria to ensure that the trial conforms to appropriate scientific and ethical standards. In addition, the MMA established additional criteria for trials initiated before January 1, 2010 to ensure that the devices involved in these trials are intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Seven commenters were in favor of this provision. Of them, four had additional comments. One commenter was against the provision.

Comment: One commenter stated that this provision would result in money being taken away from the pool of money for physician payments of non-experimental procedures.

Response: We considered this issue in determining the SGR for 2005. Since we have made a regulatory change to allow for coverage of routine costs associated with Category A clinical trials, we are required by statute to reflect any increased costs of this policy in the 2005 SGR. At this time, we are estimating that the costs associated with coverage of routine costs of Category A clinical trials will increase Medicare spending for physicians' services by less than 0.1 percent. However, we are reviewing this issue and we will adjust our estimates once we have actual spending data for 2005.

Comment: One commenter specifically requested that we define routine costs.

Response: We discuss and define routine costs in section 310.1 of the Medicare National Coverage Determination Manual (pub 100.3). We will take this comment into consideration if we decide to revise section 310.1 in the future.

Comment: Two commenters recommended that we adopt a definition of ''immediately life-threatening'' that would allow contractors some level of flexibility when they apply this criteria to evaluate trials.

Response: We will consider the importance of some level of flexibility in defining ''immediately life-threatening.'' Although we are not defining this term in our regulation, we intend to provide guidance through implementing instructions.

Comment: Another commenter suggested that contractors determine in advance if trials satisfy the immediately life threatening requirement.